copernicus group independent review board

Approved: 22May2018

SUBJECT INFORMATION AND CONSENT FORM AND HIPAA AUTHORIZATION

Name of Research Study: A PHASE II, MULTICENTRE, DOUBLE-BLIND, RANDOMISED, PLACEBO-CONTROLLED, DOSE ESCALATION AND DOSE FINDING STUDY TO EVALUATE THE EFFICACY AND SAFETY OF DYSPORT IN VULVODYNIA PATIENTS

Study #: D-FR-52120-236

Sponsor: Ipsen Innovation

Investigator: **Andrew Todd Goldstein MD**

Research Site Address(es):

The Center for Vulvovaginal Disorders
3 Washington Cir NW Ste 205
Washington DC 20037

Daytime Telephone Number(s): 202-887-0568

24-hour Contact Number(s): 410-279-0209

You are invited to participate in a clinical research study, which is being sponsored by a drug company called IPSEN. Before you decide whether you wish to take part it is important for you to understand why the study is being conducted and what it will involve if you agree to take part in it. Please read this subject information and consent form carefully and discuss it with others if you wish. This form provides information about the purpose, possible benefits, risks, discomforts and other treatment alternatives. Your doctor and/or a member of the study staff will also explain the study to you in detail. It is important that you read this information carefully and ask as many questions as necessary to make sure you understand the study.

Take time to decide whether you wish to take part. If you decide to participate, you will be asked to sign and date this form. Such consent will be the legal basis for the processing of your information. If you decide not to consent, you will still receive the best available treatment.

WHAT IS THE PURPOSE OF THIS STUDY?
The purpose of this research study is to evaluate the efficacy, safety and identify the optimal doses of Dysport in the treatment of vulvodynia. In this study, Dysport will be compared to a placebo treatment (i.e. dummy treatment that looks like the real treatment but contains no active ingredient).

WHAT IS THE DRUG BEING TESTED?
Dysport contains a toxin that is produced by a bacterium. The toxin is called Botulinum toxin A and is known to cause muscle relaxation.

Dysport was first approved in the United Kingdom (UK) in 1990 and is now approved in more than 85 countries including the United States (US), for the treatment of conditions where the muscle needs to relax. Dysport is experimental and is not approved by the Federal Drug Administration (FDA) for the treatment of vulvodynia.

WHY HAVE I BEEN CHOSEN?
You have been asked to participate because you have a condition called provoked vestibulodynia, the most common form of vulvodynia, which causes pain at the entrance of your vagina when pressure is applied in this area. It is thought the pain is due to an over contraction of your pelvic floor muscles.

Other studies done with Dysport or other Botulinum toxin A for vulvodynia and other related conditions (like vaginismus), have shown to relax the pelvic floor muscles and decrease pain.

If you agree to take part in this research study, you will be one of approximately 93 subjects that will be enrolled in this study.

DO I HAVE TO TAKE PART?
It is up to you to decide whether you take part in this study – it is entirely voluntary. If you prefer not to take part, you do not have to give a reason and your doctor will decide the best course of treatment for you. If you do decide to take part, you are free to

withdraw at any time, without giving a reason. No additional information about you will be collected by IPSEN after this time. If you do decide to withdraw during the study because of a side effect, it is important that you tell your study doctor about the side effect, if possible.

There will not be any penalty or loss of benefits to which you are otherwise entitled if you decide not to take part or if you leave the study early.

Subjects will enter the study by sequential groups, with different doses of study treatment. The dose you receive will depend on when you enter the study. If the recruitment in a group is complete at the time you can begin the study treatment, your doctor may propose you to take part in the study at a later stage once a new group is started. If you have a urinary or vaginal infection preventing you to begin the study treatment, your doctor may also propose you to take part in the study at a later stage, providing the infection has been cured in the meantime. In those cases, and if you agree, you will be asked to sign a new informed consent form and re-do screening assessments described below.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

If you decide to participate in this study, the investigator will determine if you meet the study requirements before you begin treatment. Your participation in this study could last from 38 weeks (9.5 months) to a maximum of 54 weeks (1 year) and include from 8 to 10 study visits. The study consists of a screening visit, a baseline visit (where treatment with Dysport or Placebo will be administered) and follow-up visits every 6 weeks (including possible re-treatment(s) with Dysport).

Screening Visit

After you have signed the informed consent form, the following procedures will be done:

- Physical examination, review of your medical/surgical history, review of medications/therapies you are taking or have taken, recording of your demographic data (date of birth, age, sex, ethnicity, and race), body height and weight.
- Measurement of your vital signs (blood pressure and pulse).
- Collection of blood sample (approximately 20 mL or 4 teaspoons) for lab tests, such as analysis of the cells, chemicals, hormones and antibodies contained in your blood. Antibodies sometimes develop after treatments such as botulinum toxins. It may mean that the treatment is no longer as effective, as the antibodies may stop the effect of the drug.
- Collection of urine sample for pregnancy test and drug screen for illegal drugs.
- Vaginal swab to check for infection impacting your vulvodynia condition.
- Completion of questionnaires on an electronic device (such as a tablet) about your vulvar pain, sexual function, and health (duration approximately 25 minutes).
- Q-tip test. Your doctor will use a cotton swab/cotton-tipped applicator to touch the entrance of your vagina and identify the area where you have pain.

- Dilator test. Your doctor will use a set of 8 silicone vaginal dilators of different sizes to evaluate your vulvar pain. Your doctor will insert each dilator to a depth of 3 to 4 cm into your vagina, starting with the smallest size (equivalent to a regular size tampon). The doctor will insert dilators of increasing size until you have reached the largest size you can tolerate. You will be asked to rate the pain intensity for each dilator size.
- You will be asked to complete an electronic diary until the next visit:
    - Daily: answer questions about the number of times you had sexual intercourse in the previous 24 hours, related pain intensity and medication you may have taken to prevent or treat this pain.
    - Weekly: You will be asked to insert a dilator equivalent to the size of a penis into your vagina, rate the related pain intensity and record the medication you may have taken to prevent or treat the pain.
    - Weekly: answer questions about your vulvar pain and your partner relationship status.

Entry into the study will depend upon the results from the screening procedures, the information you provide, the study specific guidelines and criteria, and the discretion of your doctor. We ask you to be honest and provide accurate and complete information. Giving false, incomplete, or misleading information could put your health at risk.

Treatment Visit

Depending on the stage of the study, you will be asked to come for the treatment visit 2 weeks or 1 month after the screening visit.

Before the study treatment, your doctor will review with you any side effects you have experienced and the details of any medication / non-drug therapies you have used since the last visit to ensure you are still qualified to participate in the study. You will then be asked to perform the following procedures:

- Completion of questionnaires on the electronic device about your vulvar pain, your sexual function, mood, and quality of life (depending on the stage of the study) (duration approximately 30 minutes).
- Dilator test.
- Measurement of pelvic floor muscle pressure. Your doctor will insert a sensor in your vagina (equivalent to a regular size tampon). You will be asked to squeeze and relax few times.

For your first treatment, you will randomly (like a flip of a coin or drawing straws) receive either Dysport or placebo. Your chance of receiving Dysport or placebo may vary depending on the stage of the study (it could be 4 in 1, 2 in 1 or 1 in 1). This first treatment is double blind which means that neither you nor your doctor will know what treatment you receive. Although, if your doctor needs to know it in an emergency, he/she can find out. Different doses of Dysport, from 100 units to a maximum of 400 units will be evaluated in the study. The dose you will receive will be determined by a data review committee based on the results of the previous subjects who have received the Dysport in this study.

Your doctor will inject the study treatment into 5 sites in the pelvic floor muscles at the entrance of your vagina. You will be observed during at least 30 minutes after the injection before leaving the clinic.

You will also be asked to complete the electronic diary during 1 month prior to the next visit as described above:

- Daily: questions related to intercourse
- Weekly: dilator insertion, questions related to vulvar pain and relationship

Two weeks after the treatment visit, your doctor or the study staff will contact you by phone to see how you are feeling, if you have experienced any side effects, and the details of any medication / non-drug therapies you have used since the treatment visit.

Treatment Follow-up Visit

Every 6 weeks from the treatment visit, you will be asked to perform the following assessments:

- Completion of questionnaires on the electronic device, about your vulvar pain, your sexual function, mood (at 12 weeks and last treatment follow-up visit only), quality of life (depending on the stage of the study, at 12 weeks and last treatment follow-up visit only) (duration approximately 10 to 30 minutes).
- Review any side effects you have experienced and any medication / non-drug therapies you have used since the last visit.
- Collection of blood sample (approximately 7 mL or 1.5 teaspoons) for lab tests (at 12 weeks only).
- Collection of urine sample for drug screen for illegal drugs (at 6 weeks only).
- Dilator test.
- Measurement of pelvic floor muscle pressure.

You will also be asked to complete the electronic diary during 1 month prior to the next visit as described above:

- Daily: questions related to intercourse
- Weekly: dilator insertion, questions related to vulvar pain and relationship

From 12 weeks (3 months) onwards, you will decide with your doctor if you need to receive additional study treatment. If yes, you will perform a Re-Treatment visit on the same day (or few days after if your doctor prefers to wait for the committee to confirm the dose allowed); If no, you will come back every 6 weeks for Treatment Follow-up visits until you need to be re-treated or reach 36 weeks (9 months) from the first study treatment.

Re-Treatment Visit

Before being administered with a new injection of study treatment, the following procedures will be done:

- Collection of urine sample for pregnancy test and drug screen for illegal drugs
- A physical examination and review of any side effects you have experienced and any medication / non-drug therapies you have used since the last visit.

If the visit occurs more than 1 month after the last visit, you will be asked to re-do the following procedures:

- Completion of the electronic diary during 1 month prior to the next visit as described above:
    - Daily: questions related to intercourse
    - Weekly: dilator insertion, question related to relationship
- Completion of questionnaire on the electronic device to rate your condition (duration approximately 2 minutes).
- Dilator test.

For your re-treatment, you will receive Dysport. A maximum of 3 re-treatments is possible, with at least 12 weeks between each treatment. The dose of Dysport will be decided by your doctor based on the previous committee recommendation and your personal need.

You will be injected with Dysport and observed in the same manner as for the first treatment.

You will be asked to complete the electronic diary during 1 month prior to the next visit as described above:

- Daily: questions related to intercourse
- Weekly: dilator insertion, question related to relationship

You will also be contacted by phone two weeks after each re-treatment visit to see how you are feeling, if you have experienced any side effects, and any medication / non-drug therapies you have used since the re-treatment visit.

Re-Treatment Follow-up Visit

Every 6 weeks from the Re-Treatment visit, you will be asked to perform the following procedures:

- Completion of questionnaire on the electronic device to rate your condition (duration approximately 2 minutes).
- Review if you have experienced any side effects and the details of any medication / non-drug therapies you have used since the last visit.
- Collection of urine sample for drug screen of illegal drugs (at 6 weeks only).
- Dilator test.

You will also be asked to complete the electronic diary during 1 month prior to the next visit as described above:

- Daily: questions related to intercourse
- Weekly: dilator insertion, question related to relationship

If this visit occurs more than 9 months after the first study treatment, you will be asked to perform the End of Study Visit on the same day.

If this visit occurs 9 months or less after the first study treatment, you may decide with your doctor if you need to receive additional study treatment. If yes, you will perform a Re-Treatment visit on the same day (or few days after if your investigator prefers to wait for the independent committee to confirm the dose allowed) and further re-treatment follow-up visits; If no, you will come back every 6 weeks until you need to be re-treated or reach more than 9 months (maximum 12 months) from the first study treatment to complete the end of study visit on the same day.

End of Study Visit or Early Termination Visit

If you are withdrawn from the study, or choose to withdraw from the study, or if you reach the end of study, you will be required to meet with your study doctor for final assessments. You will not have to re-do any of the assessments listed below if you have already done them at a follow-up visit on the same day:

- Completion of questionnaires on the electronic device to rate your condition, mood and quality of life (depending on the stage of the study) (duration approximately 10 minutes).
- Review if you have experienced any side effects and any medication / non-drug therapies you have used since the last visit.
- Collection of blood sample (approximately 20 mL or 4 teaspoons) for lab testing.
- Collection of urine sample for pregnancy test and drug screen for illegal drugs.
- Dilator test.

WHAT DO I HAVE TO DO?

All changes in your health during the study must be reported to your doctor or a member of the site staff, regardless of whether you think that these changes are related to the study. During the whole study, you will be monitored for new symptoms, new diseases, side effects, other medications and compliance with the appointment schedule.

During your study participation you are not allowed to use any medication that interferes with the study treatment, including:

- Any form of botulinum toxin for administration into any other part/site of your body,
- Any experimental new drug (or device),
- Illicit drugs,

- Medications that affect the neuromuscular transmission, such as curare-like nondepolarizing agents, lincosamides, polymyxins, anticholinesterases and aminoglycoside antibiotics (topical use is permitted if not at the vulva).
- Topical lidocaine, topical antidepressants, topical anti-epileptics and diazepam suppositories. Note: immediately before and during study drug administration procedures, oral, topical (other than lidocaine) or intravenous medications routinely used as standard of care for vaginal intramuscular injections may be used by your clinician.
- Medications that affect bleeding disorders (antiplatelet agents and/or anticoagulants) that might interfere with local injections or medications that contraindicate injection into the muscles.

You will be asked to stop pelvic floor physical therapy and sex therapy (if focused on the management of your vulvar pain) for the screening period and up to 6 weeks after the first treatment cycle. If you start any pelvic floor physical therapy or sex therapy after this, it will need to be done at the same frequency/regimen throughout the study. Physical therapy includes but is not limited to internal/external myofascial release by physiotherapist, biofeedback, home pelvic floor exercises, and self-taught exercises.

The following medications are permitted during this study, but they must be monitored closely and should be taken at the same frequency and dose during the study:

- Antidepressant, anxiolytics or anti-epileptics to treat vulvar pain,
- Anticholinergic drugs,
- Other analgesics or topical hormonal cream if stopping is not possible or indicated,
- Pain rescue medication taken to prevent or treat vestibular pain should be avoided but can be taken as per your need and as far as possible kept the same. If needed you will be allowed to take nonsteroidal anti-inflammatory drugs (NSAIDS) or Acetaminophen at the recommended dose. However, you should refrain from taking any rescue medications within 24 hours of a study visit You will be asked to record in the eDiary the analgesic taken prior or after intercourse/dilator insertion for vestibular pain.

During the study, you will be encouraged to follow the lifestyle restrictions below:

- abstain from illegal drugs,
- avoid vulvar irritants such as perfumes, deodorants, or soaps,
- avoid modifying your hygiene habits,
- wear only cotton underwear.

WHAT ARE THE ALTERNATIVES FOR TREATMENT?

If you choose not to participate in this study, your doctor will discuss possible alternative treatments, including their benefits and risks with you, as the availability of these treatments may affect your decision to participate in this study.

There is currently no approved drug for the treatment of vulvodynia. Other treatment options may include psychological treatments, physiotherapy, use of medications not approved by the FDA, and possibly surgery.

WHAT SIDE EFFECTS CAN BE EXPECTED?

Dysport

Most drugs have side effects associated with them. It is possible that rare or unforeseeable side effects, which could be serious, may occur.

Dysport is generally well tolerated although temporary paralysis of non-targeted muscles can occur. In general, the side effect depends on the site of injection and are of mild or moderate severity and of limited duration.

Based on published data for the treatment of vulvodynia and other related conditions (like vaginismus) with Dysport or similar treatments, urinary incontinence and faecal incontinence may occur.

Side effects, commonly seen with the use of Dysport in any location, are:

- general weakness,
- tiredness,
- flu-like illness and
- injection site reactions, such as pain or bruising.

Much more uncommon reactions include itching and rash. Hypersensitivity (allergic reaction) may occasionally be experienced.

Some signs that you may be having an allergic reaction are:

- Rash or hives
- Having a hard time breathing
- Wheezing when you breathe
- Sudden change in blood pressure (making you feel dizzy or lightheaded)
- Swelling around the mouth, throat or eyes
- Fast pulse
- Sweating

You should get medical help and contact the study doctor or staff if you have any of these or any other side effects during the study.

Side effects of Dysport to parts of the body away from the site of injection have been rarely reported. These include:

- excessive muscle weakness,
- difficulty speaking,

- difficulty breathing or swallowing which may lead to aspiration pneumonia (lung infection), which can result in death in extremely rare cases in patients.

Please contact your doctor immediately if you experience any such symptoms. Excessive muscle weakness after Dysport injection may impair your ability to drive.

As with any drug, there may be side effects not known at this time. Side effects may go away after the treatment is stopped, but it is also possible that side effects may last a long time or may never go away. They may range from mild to life threatening and/or fatal.

It is important that you report to your study doctor all symptoms and side effects that you experience (however mild or severe), as soon as they appear, whether or not you think they are related to the study drug.

Blood Draw/Study Drug Injection
You may feel some discomfort when the needle is placed in your vein to draw blood for testing or in your vulva for study drug injections. Sometimes a bruise may develop where the blood was drawn, or the needle was placed, and occasionally infection or bleeding may develop at the puncture site. Light-headedness and/or fainting may occur during blood collection.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?
If you receive placebo for the first study treatment, your vulvodynia condition may stay the same or might get worse. In this study, you will receive Dysport if you have more than 1 study treatment. However, as the study medication is experimental, even if you receive active drug, it may not help your vulvodynia condition, which may stay the same or might get worse.

Reproductive Risks
If you are capable of becoming pregnant, you must agree to use highly effective form of contraception during the study and for at least 12 weeks after your last administration of study drug. For this study, highly effective methods of contraception include:

- implants,
- injectables,
- combined oral contraceptives,
- some intrauterine devices,
- vasectomized partner,
- double barrier method (condom and spermicide) if determined appropriate for you by your doctor.

Please discuss your method of contraception with the study doctor to ensure that it is acceptable.

You may not take part in this study if you are pregnant or nursing a child. Due to the unknown risk to an unborn or nursing infant, you must not become pregnant during the study. If you become pregnant or suspect that you are pregnant while participating in this study, you must notify your doctor immediately. Your will not receive further Dysport administration and your pregnancy will be tracked until its completion.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?
The study treatment (Dysport or placebo) may or may not help your condition. You should also be aware that you may not benefit from this treatment. However, it is hoped that the information gained from the study will help in the treatment of future patients with vulvodynia, provide relief from vulvar pain, subsequently improve sexual function and quality of life.

WHAT IF NEW INFORMATION BECOMES AVAILABLE?
If new information becomes available, your doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your doctor will make arrangements for your care to continue. If you decide to continue in the study, you will be asked to sign an updated consent form.

Also, on receiving new information your doctor might consider it to be in your best interests to withdraw you from the study. Your doctor will explain the reasons and arrange for your care to continue.

WHAT HAPPENS WHEN THE RESEARCH STOPS?
Your participation in the study may be stopped by your doctor or IPSEN with or without your consent at any time for any reason, including:

- You experience an undesirable side effect,
- You do not follow the study instructions,
- The doctor or IPSEN think it would be in your best interest to withdraw from the study,
- IPSEN or the FDA stops the study for any reason.

Should this happen, your doctor will decide the best course of treatment for you. If you stop the study early, you might be asked to undergo any laboratory tests and examinations that your doctor considers necessary.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?
All information relating to you and collected from you during the study will be kept confidential.

IPSEN will be the data controller with respect to the processing of the personal data collected as part of this study. During the study, only the data that can be collected in accordance with applicable laws and regulations will be used, such as your year of birth, age, gender (male or female), race, ethnicity and all the medical information relevant for the study objectives. The information collected will be identified by a study subject number, not with your name.

The collected data will be transferred to IPSEN and companies acting on behalf of IPSEN, and only to individuals who are involved in the study conduct, analysis, reporting and regulatory submission.

Federal regulations give you certain rights related to your health information. These include the right to know who will receive the information and how it will be used. The study doctor must obtain your authorization (permission) to use or release any health information that might identify you.

WHAT INFORMATION MAY BE USED AND SHARED?
The study doctor and study staff will use and share your health information as part of this research study. Except when required by law, you will not be identified by name, address, telephone number or other facts that could identify the health information as yours.

Examples of the information that may be used are:

- Medical records (from any doctor, hospital or other healthcare provider)
- Information created or collected during the research. This could include your medical history, and dates or results from any physical exams, questionnaires, laboratory tests or other tests.

By consenting to participating in this study, you authorize processing, access to or consultation of your information, including your medical records by:

- the individuals or entities involved in the conduct of this study and mandated by IPSEN,
- Copernicus Group Independent Review Board (CGIRB). The IRB is a group of scientists and non-scientists who review the ethics of research. The goal of the IRB is to protect the rights and welfare of study subjects.
- relevant regulatory authorities (FDA).

for verification of clinical trials procedures and/or data, without violating the confidentiality of the information, to the extent permitted by the applicable laws and regulations.

By signing this informed consent form, you are allowing direct access to your medical records as set out above.

Your health information may be further shared by the groups above. If shared by them, the information will no longer be covered by this Authorization. These groups are committed to keeping your health information confidential.

You do not have to sign this form. If you do not sign this form, you cannot take part in this research study.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?
Information collected from you and all other subjects taking part in this study will be saved and processed using validated computerized systems for analysis.

IPSEN will contract and assign the processing of this data to a company that has experience on how to collect and analyse such data safely.

Access to the data will be restricted to authorized personnel only.

The results of this research study may be given to regulatory authorities such as the FDA, published, or presented at scientific meetings and may be used for further research. You will not be identified in any publications or presentations.

The study data may be used, after the end of the study, outside this research study for further analysis. In this case, only dedicated employees for the analysis from IPSEN or companies acting on behalf of IPSEN will have access to your data, which will remain confidential.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

YOUR RIGHTS WITH RESPECT TO YOUR INFORMATION.
You may change your mind and revoke (take back) the authorization to use your information. To revoke the authorization, contact your doctor in writing.

If you withdraw your permission, you will not be able to continue being in the research study.

Information that has already been gathered may still be used and given to others. If you withdraw your permission, no new health information will be gathered unless you have a side effect related to the study.

If you withdraw from the study but do not withdraw your Authorization, new health information may be collected until this study ends.

If you do not withdraw this Authorization, it will remain in effect.

If the research site is located in California, Delaware, Indiana, Washington, or Wisconsin, this authorization will expire on 31Dec2060.

There is no expiration of this authorization except for research conducted in the states listed above.

Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are otherwise entitled.

You also have the right to lodge a complaint with a data protection authority if you are not satisfied with the way IPSEN processes the information.

The contact details for IPSEN Data Protection Officer is dataprivacy@ipsen.com.

CAN I CHANGE MY MIND ABOUT TAKING PART IN THIS RESEARCH PROJECT?
Taking party in this study is your choice. You can withdraw your consent at any time and for any reason during the study and can do so by contacting your doctor.

If you decide to stop participating in this study, your doctor will not use or release any new information about you. Information obtained before you withdrew can be used for the study.

You will not be allowed to review your personal data during the study, but you have the right to review it after the study is completed.

COSTS
The study treatment and study-related procedures will be provided at no cost to you.

The sponsor is paying for this research study. Your study doctor will be paid by the sponsor.

COMPENSATION
You will receive $40.00 for each study visit you complete, except days of injection when you will receive $75.00 for completed visit. Payment will be made at the end of your participation in the study.

COMPENSATION FOR ILLNESS OR INJURY
Your doctor will make every effort to prevent physical injury that could result from this research. If you sustain an injury or illness determined by your doctor as a direct result of participating in this study, you will be reimbursed by IPSEN for reasonable medical expenses necessary for the treatment of the injury or illness that are not covered by your health insurance, provided that the study medication administration and the study procedures were according to the study protocol. IPSEN will not compensate you for any unrelated or pre-existing medical conditions or any complications not directly caused by participating in this study.

QUESTIONS
If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to them at (888)-303-2224, irb@cgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Do not sign this form unless you have had a chance to ask questions and are happy with the answers to all your questions. If you agree to take part in this study, you will be given a copy of this information sheet and of the signed consent form to keep.

SUBJECT'S STATEMENT OF CONSENT

1. I confirm that I have read and understood the information in this form.
2. I have been given enough time to consider the study and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that sections of my medical information may be looked at by responsible individuals from IPSEN or its representatives or from regulatory authorities and / or IRBs / ECs where it is relevant to my taking part in research. I give my permission for these individuals to have access to my records and to use such records for the purposes as described in this form. I also give permission for my coded data to be archived and for its transfer outside the United States of America, in accordance with the national laws on processing of personal data.
4. I agree to voluntarily take part in the above study and to have my information processed for this purpose in the manner described above.
5. I will receive a signed and dated copy of this informed consent form.

Subject's Name	Subject's Signature	Date
Investigator's/Delegate's Name	Investigator's/Delegate's Signature	Date

Statement of the Witness (when applicable*)
The information in the consent form was accurately explained to, and appeared to be understood by the subject. Informed consent was freely given.

Impartial Witness's Name (if applicable)	Impartial Witness's Signature	Date

*Impartial Witness: If the subject cannot read, the signature of an Impartial Witness is needed.

An impartial witness is:

- a person who is independent of the trial,
- who cannot be unfairly influenced by people involved with the trial,
- who attends the informed consent process, and
- who reads the informed consent form and any other written information supplied to the subject.