PATIENT INFORMATION SHEET

Protocol Title: "A Multicenter, Open-Label, Single-Arm, Phase II Clinical Trial to Evaluate the Efficacy and Safety of INCMGA00012 in Advanced Penile Squamous Cell Carcinoma".

Phase II Study of the Efficacy of INCMGA00012 in Penile Squamous Cell Carcinoma (ORPHEUS)

EudraCT#: 2019-001172-11

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Study Sponsor: Medica Scientia Innovation Research, SL (MedSIR)

Investigator: *[For site-specific ICF: Insert Investigator's name and contact information (i.e. phone number and address if different from institution address below)]*.

Institution: *[For site-specific ICF: Insert institution name and address]*.

Overview

You are being asked to take part in a clinical research study of an investigational drug. Before you agree to take part in this research study it is important that you read and understand this document.

This document describes the purpose, procedures, responsibilities and potential risks and benefits involved in taking part in this clinical trial. In this document you will also find the alternative procedures that are available to you and your right to withdraw from the study at any time without having to give any reasons and without this being detrimental to your health care.

If this document uses any terms you do not understand, or you have any question, ask your doctor or a member of the staff involved in the clinical trial to explain it to you. If you decide to take part in this study, you will be asked to sign this consent form. A copy of this signed form will be given to you to keep.

What is this purpose of this study?

We invite you to participate in this research study because you have been diagnosed with a penile squamous cell carcinoma that cannot be treated with surgery with curative intent (called

"unresectable locally advanced or metastatic penile cancer"). You have received prior chemotherapy regimens or radiotherapy (or not) but you have just recently progressed.

The main purpose of this study is to assess the efficacy of INCMGA00012 in patients who has unresectable locally advanced or metastatic PSqCC.

You should know that there are other treatments for the type of penile cancer that you have. The study doctor will discuss with you about the possible advantages and disadvantages of being part of this study as well as other options treatments that you can choose.

This study includes also additional scientific research to analyze your proteins and genes, which are stored in almost every cell in your body and provide the instructions to doing their jobs properly. The first goal of this research is to determine the status of different genes and/or proteins, that could be used as potential markers of tumor reproduction; and the second goal is to assess whether the status of these markers is related to treatment response. The analysis of human biological materials and data obtained or to be obtained from them has been recognized as an important instrument for current and future medical research.

Blood and tissue samples collected in this study will be used to perform research studies related to the objective of the current research.

Who is sponsoring and conducting this research?

This research study is being sponsored globally by Medica Scientia Innovation Research, SL (MedSIR).

Who has reviewed this research?

This study has been approved by *{Name of IRB/EC}*, an organization that is responsible for protecting the rights and safety of patients who take part in research studies in your country.

How many people will take part in the study?

About 18 patients from different hospitals located in several countries in Europe are expected to take part in this clinical trial.

What will happen if I take part in this research study?

You are being asked to take part in this study because you have been diagnosed with Unresectable locally advanced or metastatic penile squamous cell carcinoma (PSqCC) and your doctor thinks

that you are a good candidate to receive INCMGA00012 treatment. Your study doctor will confirm to you whether you meet other clinical criteria necessary to take part in the study.

Before you begin the study, you will need to undergo the following tests or procedures to find out if you can be included in the study. Some of them may be part of your regular medical care and may be done even if you do not take part in the study. If you have had some of them recently, they may not need to be repeated.

- Discussion of this study and review and signing of this Informed Consent Form.
- Recording of your demographic information, including your age.
- Review of your medical history and any medications (including herbal or dietary supplements) that you are taking or have taken within the last 28 days.
- Complete physical examination.
- Measurement of your height and weight.
- Measurement of your vital signs (respiratory rate, heart rate, blood pressure, and body temperature).
- The extent of your disease to the thorax, abdomen, and pelvis will be also evaluated by the following medical imaging techniques, commonly used in radiology: computerized scan (CT) or magnetic resonance imaging (MRI) and bone scan.
- Electrocardiogram (ECG). An ECG is a measurement of the electrical activity of your heart.
- Collection of about 10 mL of blood for standard laboratory tests (including blood chemistry and blood cells count).
- Viral serology and Mantoux tuberculin skin test (TST) to confirm eligibility.
- Collection of urine to analyze pH, glucose, protein, ketones, and blood.
- Assessment of any side effects associated with screening procedures.

If you agree, and the study doctor determines that you are a suitable candidate to participate in the trial, you will be included in the study.

If you decide to take part in this research, several samples of blood and tumor need to be collected for genetic research. Participation in this research will not result in any changes to the type of treatment you are receiving or will receive later.

If you consent to participate in the study, blood samples (up to 20 mL of blood) will be collected for genetic analysis before first dose of study treatment, after 8 weeks from treatment initiation, and at the end of study (prior to start alternative anticancer therapy). A whole blood aliquot will be preserved to obtain DNA and compare genetic data from tumoral and normal tissue. These blood samples will be collected in addition to any blood samples that will be drawn for the purpose of your medical care.

By signing this document you also authorize the collection of tumor tissue from metastatic lesions, whenever possible. This biopsy might be part of the standard clinical care or could be done specifically for this research. In case the collection of the metastatic sample is not possible, the archival sample obtained during the initial diagnosis may be used for this research study.

During study treatment

If you are finally included in the study, you will receive INCMGA00012 500mg by intravenous infusion on Day 1 of each cycle, once every four weeks for up to 2 years.

During the treatment period you will be asked to attend to the clinic at least once every 4 weeks where you will undergo the tests and procedures described below. All these procedures are part of the standard clinical care for your disease, unless it is indicated otherwise.

During all the study visits, you will be asked about any changes in your health since the previous visit. The treatment side effects will be written down exactly as you tell your doctor.

You will have a physical check-up including weight and vital signs within 72 hours prior to Day 1 of each cycle (every 4 weeks), prior to the end of treatment visit and prior to the end of the study.

A basic routine blood test (approximately 10 mL of blood) will be done by the study personnel to check the number of cells in your blood and how well your liver and kidneys are working. Before study treatment administration, a urinalysis will be done (every 2 cycles).

The extent of your disease will be also evaluated by thorax, abdomen, and pelvis CT scan or MRI every 8 weeks during the 6 initial months of treatment and every 12 weeks afterwards. If you have a known history of bone metastases or have new bone pain during screening, a bone scan should be obtained prior to study entry. A bone scan at follow-up will be required only in case that you develop new or worsening symptoms

ECGs should be performed before prior to study entry. Additional ECGs will be repeated as per your doctor decision.

If you consent to participate in this study, you should use a barrier contraceptive method (e.g. condom with spermicidal foam) or maintain sexual abstinence.

You should continue to use highly effective methods of contraception throughout the trial and up to 180 days following the end of the study treatment.

How long will I be in the study?

You will continue to receive the study treatment until the confirmation of progressive disease, unless treatment has to be interrupted because your doctor considers it is harmful or have unacceptable side effects.

If you have a serious side effect during the study, the study doctor will ask you to visit the clinic for follow-up examinations, even after you have completed your regular study visits.

What are my responsibilities?

As a participant in this trial, you have certain responsibilities that will help to ensure your safety is properly guaranteed during the study. These responsibilities are:

- Keep your study appointments. If you cannot keep an appointment, contact your study doctor or study staff to reschedule as soon as you know that you will miss the appointment.
- Tell your study doctor or study staff about any medications you are taking.
- Inform your doctor or any study staff about any side effects, other doctor visits, or hospitalizations that you may have whether or not you think they are related to the study treatment.
- Tell your study doctor if you have been in a research study in the last 28 days or are in another research study now. While participating in this research study, you cannot take part in any other research study.
- Inform your doctor if you do not wish to continue receiving treatment as part of the clinical trial. In this case, you will be asked to attend a study final visit.
- Inform your doctors that you are taking part in this study.
- Carry with you at all times during the study a card that states that you are taking part in this study.

Will I be told about new information?

During the study, you will be told in a timely manner about new information or changes in the study that may affect your health or your willingness to continue in the study. If based on this potential new information, you agree to continue in the study, you will be asked to sign an updated Consent Form.

Are there benefits to taking part in the study?

Taking part in this study may or may not involve any type of direct medical benefit to you. While doctors hope that treatment with INCMGA00012 could be beneficial against penile cancer, there is no proof of this yet.

It is possible that your participation in this study could benefit future penile cancer patients thus contributing to the development of possible future treatments and can help doctors to learn more on this condition.

What side effects or risks and discomforts can I expect from being in the study?

Although medication is carefully studied before being administered to humans, adverse events may occur.

Besides the side effects described below, there may be other side effects that are currently unknown. You or your legal representative will be properly informed if new information on the medication used in this study comes to light that may be relevant to you continuing to take part in the trial. If your doctor decides to stop the study treatment because of an adverse reaction you will be offered alternative treatment your doctor considers more appropriate in your case.

Risk and side effects related to lNCMGA00012

Adverse reactions for INCMGA00012 is mainly based on data collected in clinical trials. Risk and side effects are classified by frequency, with the most frequent shown at the beginning:

- Very common (in ≥ 10%): Fatigue (tiredness or lack of energy), diarrhea, nausea, and fever
- Common (< 10 % and ≥ 1%): ALT increased (high levels of an enzyme produced by the liver), colitis (inflammation of the large intestine), abnormal taste, hyperthyroidism (overactive thyroid gland), hypothyroidism (underactive thyroid gland), flu-like illness, infusion-related reaction, lipase increased (abnormal digestive blood test), muscle pain, itching, rash (includes different types of rash, such as itchy rash or rash all over the body or rash that looks like a flat, red area on the skin that is covered with small merging bumps)
- Rare, but serious (< 1%): Pneumonitis (lung inflammation, possible difficulty breathing)

Possible risks and discomfort associated with drawing blood

During this study, small amounts of blood will be drawn from a vein and used for tests that allow your study doctors to see how you are doing. Drawing blood may cause pain where the needle is inserted, and there is a small risk of bruising or infection at the place where the needle is inserted. Some people experience dizziness, upset stomach, or fainting when their blood is drawn. Precautions will be taken to avoid these side effects. Whenever possible, blood for the additional scientific research discussed above will be drawn at the same time as samples for other required laboratory tests. If not, an additional needle stick may be required.

Risks associated with obtaining biopsies

Tissue biopsies will be obtained during the study. The risks associated are pain, bruising, perforation, or penetration of the needle into the blood vessels which may produce bleeding, infection, color changes, and blood clots. All precautionary measures will be taken to ensure that the biopsy procedure will have the smallest chance of possible risks.

Risks associated with unauthorized use of data in scientific research

Strict privacy and confidentiality procedures for this research have been adopted (For major details, please see section "**How will health information that identifies me be used and disclosed?**"). However, there is still very small risks associated with a loss of privacy or confidentiality. For example, if your identity as a participant in scientific research or your identifiable genetic or health information were disclosed to unauthorized persons, there is the possible risk of discrimination by employers or insurance providers.

Possible risks and discomfort associated with CT scans

CT scans are special X-ray tests used to study the internal organs and bones of your body, and they are necessary for measuring your response to this treatment. You would likely undergo these scans even if you were not participating in this research study because your doctor would need to monitor your disease.

You will be exposed to radiation from CT scans approximately every 8 weeks every 8 weeks during the 12 initial months of treatment and every 12 weeks afterwards. Scientists disagree on whether radiation doses at these low levels are harmful. A possible effect that could occur at doses associated with this study is a slight increase in the risk of developing cancer later in life. Since the effects of radiation can build up over time, it is important to know of your past radiation exposure. If you have been exposed to radiation through CT scans, X-rays, or other means in the past 12 months, please inform study personnel. If it is determined that your prior radiation exposure exceeds current guidelines, it is possible that you will not be allowed to participate in this study for safety reasons.

As part of the CT scan, a contrast agent may need to be taken by mouth and/or injected into your vein to make certain organs and disease sites visible on the scan. Oral contrast may cause side effects such as nausea, constipation, diarrhea, and abdominal bloating. Pain, bruising, redness, swelling, or infection may occur at the site where a needle is inserted to administer the contrast material into your vein. It is normal to experience a warm, flushing feeling when the injected contrast material is given. You may have an allergic reaction to the injected contrast material that may cause rash, hives, shortness of breath, wheezing, and itching, and rarely may cause your heart to stop beating ("cardiac arrest"). The use of contrast material during these tests would be a normal part of measuring your response to therapy, even if you were not participating in this research study.

Possible risks and discomfort associated with MRI scans

MRI scans are specialized imaging procedures that are necessary for measuring your response to this treatment. For most patients, the risks or side effects associated with undergoing MRI are minimal. An MRI scan does not involve ionizing radiation like conventional X-rays. Instead, images are generated using a magnetic field and radio signals. Because an MRI scanner uses strong magnets, you cannot have any metal implants in your body to have an MRI scan. People with an artificial heart valve, metal plate, pin, or other metallic objects in their body (including gun shot or shrapnel) are not eligible for MRI scans. Study personnel will ask you questions to make sure you can safely have an MRI scan.

There may be some anxiety and claustrophobia (fear of being in small places) associated with the scanner. Staff at the imaging center use techniques to help reduce these feelings in patients. Your study doctor may also prescribe mild sedatives or anti-anxiety drugs to help manage your symptoms. As part of the standard MRI scan, a contrast agent containing gadolinium is injected into your vein to enhance visibility. The risks associated with the contrast agent include mild nausea, headache, hives, temporary low blood pressure, chest pain, back pain, fever, weakness, and seizures. There have been reports of a severe and potentially fatal condition known as nephrogenic systemic fibrosis (a scarring condition that can lead to kidney failure) that has occurred in some patients who received gadolinium-based contrast agents. This has not been seen in patients with normal working kidneys or mild problems in kidney function. Prior to study entry, your study doctor will run tests to determine if your kidneys are working properly to make sure that the contrast agent is safe for you.

Will I be paid to participate in this study?

There will be no charge to you for your participation in this study. The study medication (INCMGA00012), study-related procedures, and study visits will be provided at no charge to you.

Examinations, scans, laboratory tests, and other medical procedures and treatments that would routinely be needed to monitor and treat your illness are known as “standard of care”. Certain standard of care services and treatments will be performed as part of your participation in the study. If you have any questions about costs to you that may result from taking part in this research study, please speak with the study team.

The costs for research-related services will be covered by the study sponsor.

Information from this study may lead to discoveries and inventions or development of a commercial product. You and your family will not receive any financial benefits or compensation from or have rights in any developments, inventions, or other discoveries that might come from this information.

What other options do I have besides participating in this study?

If you do not want to be part of this study, your treatment as prescribed by your doctor will still continue and your healthcare will not be affected in any way.

You should discuss treatment alternatives that may be right for you with your doctor.

If you decide to take part in the trial but the treatment does not manage to control your disease your doctor will provide another treatment from among those currently available that, according to his/her criteria, is most appropriate for your case.

Sample collection, storage, distribution, and destination

Samples (blood and tumor tissue for scientific research) will be sent to a sample storage facility (IMIM, Instituto Hospital del Mar de Investigaciones Medicas) located in Barcelona, España. These samples will be used for the analysis planned in the current study.

After trial period is finished, and there are remaining samples not used in the analysis planned in the present study, if you agree to do so, your samples will be maintained in a research line collection. In this case, your samples can be used for future research in penile cancer for analysis not strictly related to the objectives of the current research, and with previous approval from a Research Ethics Committee. In case you do not agree to the use of your remaining samples for future research studies in penile cancer not strictly related to the objectives of the current research, these samples will be returned to your destination center.

Once the 15-year term of sample conservation mentioned above has expired and if you give your consent, the samples not used in the planned analysis of the study and/or in future research studies of penile cancer not strictly related to the objectives of this research, and prior authorization of a

Research Ethics Committee, will be transferred to a Biobank. Otherwise, if you don't give your consent to do so, your samples will be destroyed.

How will health information that identifies me be used and disclosed?

The Study Sponsor undertakes to comply with Regulation (EU) 2016/679 of the European Parliament and of the Council, of 27 April 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (hereinafter, the "**General Data Protection Regulation**").

Both the Institution and the Study Sponsor are responsible for the processing of your data and undertake to comply with the data protection regulations in force. The data collected for the study will be identified by a code, so that no information that can identify you is included, and only your study doctor/collaborators will be able to relate this data to you and your medical history. Therefore, your identity will not be disclosed to anyone else except the health authorities, when required or in cases of medical emergency.

The Research Ethics Committees, the representatives of the Health Authority in inspection matters (Spanish Agency for Medicines and Health Products, foreign health authorities), and the personnel authorized by the Study Sponsor (study monitors, auditors), may only have access to verify personal data, clinical trial procedures and compliance with good clinical practice standards, always maintaining the confidentiality of the information in accordance with current legislation.

The data will be collected in an **investigation file under the responsibility of the Institution** and processed as part of its participation in this study.

The Investigator and the Study Sponsor are required to retain the data collected for the study for at least twenty-five (25) years after its completion. Subsequently, your personal information will only be retained by the Institution for your health care and by the Study Sponsor for other scientific research purposes, if you have given your consent to do so, and if permitted by applicable law and ethical requirements. In the latter cases, the Study Sponsor will take appropriate measures to ensure the protection of your privacy and will not allow your data to be cross-checked with other databases that may allow to identify them.

In accordance with data protection legislation, you may exercise your **rights of access, rectification, erasure ("right to be forgotten"), restriction of the processing** of data that is incorrect, request a copy of or transfer to a third party the data you have provided for the study (**data portability**), and the **right to object and not be the subject of a decision based solely on automated processing**, including profiling. To exercise your rights, please contact the principal

investigator of the study or the Data Protection Officer of the Institution at (*). We remind you that data cannot be deleted even if you stop participating in the trial, to ensure the validity of the investigation and to comply with legal duties and medication authorization requirements. You also have the right to contact the Spanish Data Protection Agency if you are not satisfied.

If you **decide to withdraw your consent** to participate in this study, **no new data will be added to the database**, but those already collected will be used.

If we transfer your encrypted data outside the European Union to entities in our group, to service providers or to research scientists working with us, your data will be protected by safeguards such as contracts or other mechanisms set up by the data protection authorities. If the participant wishes to know more about this, he can contact the Data Protection Officer of the Study Sponsor (*).

As part of this research study, your study doctor, nurses, and other {Study Site} staff will collect and record medical and personal information about you, such as information about your general health, how you have responded to the study treatment, any side effects you may have experienced, and the results of any tests performed during the study. The information collected about you will be held by {Study Site} and MedSIR. This information will remain part of the study data collected in order to protect the integrity of the study. Your participation in this study should be specified in your medical records.

To ensure that your personal information is kept confidential, your name, or any other information that allows your identification will not be entered on the forms/electronic systems or included in any records or samples the study doctor provides to MedSIR. Instead, you will only be identified by a code.

Your samples collected for scientific research will be identified with the same code number that identifies your data in the clinical part of the study.

Scientific research is not intended to provide you with clinical information. The data that is maintained in databases and created during scientific studies is for research purposes only. MedSIR will not initiate the return of any of the genetic information to you or your doctor. Information resulting from the research will not be entered into your medical records.

MedSIR may work with other laboratories, investigators, commercial or academic third parties to perform part of the analysis planned in the scientific research. If these agents assist in the research, your sample and some of your health information will be shared with them. MedSIR will ensure that these agents protect your privacy.

A clinical study report containing the results of this trial will be made available to anyone who requests a copy. Before this report is provided, additional steps will be taken to protect your information from being linked to you. If information from this study is published in a medical

journal or presented at scientific meetings, you will not be identified by name, picture, or any other personally identifying information. It is possible that this information is used and processed in scientific or medical research projects related to the drug used in this trial. You can request to be provided with general information about research studies where your data is used.

A description of this clinical trial will be available at http://www.ClinicalTrials.gov, the information will be also available in www.clinicaltrialsregister.eu [Additional web sites as per local regulations]. These web sites 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.

By signing this form, you agree to participate in this trial and agree that your personal data are used in the described conditions.

What happens if I change my mind?

Your participation in this study is voluntary. You can choose not to take part in this study at the beginning or at any time during the study, without having to give any reasons. Your decision will not have a negative effect on your present or future health care. That is, you will not receive any penalty or loss of medical benefits that otherwise you would have been entitled to.

If you wish to withdraw from the study, you should contact your study doctor. He/she will tell you the best way to withdraw from it. In this case you will be asked if your decision is related to any side effect.

The study doctor may continue to use the information collected about you prior to your withdrawal from the study. The information already sent to the study sponsor cannot be withdrawn.

At any time, the study doctor or the MedSIR group may discontinue your participation in this study without your consent. Some reasons for this to happen include you are not following the doctor´s instructions or if, in the opinion of the doctor, INCMGA00012 is not being effective drug, are harmful or has unacceptable side effects, or other reasons at the discretion of the doctor.

If you withdraw from the study, or if it finishes, you will stop receiving study medication and to ensure your safety, you will be asked to take the required medical tests and follow-up, to assess your health and safety.

MedSIR shall be entitled to retain and use any research results that were obtained prior to your withdrawal of consent. However, if you withdraw your consent and samples are not analyzed or are partially analyzed, the non-analyzed samples or the part of the samples that are not analyzed

will be destroyed, if you request to do so, but the results obtained from the part of the sample already analyzed before you withdraw consent will be retained.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him or her at the number shown below.

MedSIR will pay for the reasonable costs of immediate care for any physical injury to you that specifically result from the study drug.

MedSIR as sponsor of the clinical trial is liable for damage to your health resulting from injury caused by the study treatment and holds appropriate and adequate insurance to cover this study related damage.

There is a policy of liability insurance that covers any damage you may suffer as a result of your participation in this trial, in accordance with the regulations currently in force [include reference to applicable local regulations], that covers the legal civil liability of the policy holder, as Sponsor of the trial, of the investigator and his staff, the hospital or the site where the study is conducted and their titular, and that will provide you with the compensation and indemnity in case of impairment of your health or injuries that might happen in relation to the participation in this trial.

This insurance has been taken out with the company Chubb European Group.

You understand, however, that you have not waived any of your legal rights by signing this consent form.

Who to contact to ask questions or to report a possible injury or an adverse event related to this clinical research?

If you have any questions regarding your participation in this study or if you consider that you have experienced an injury related with this clinical trial or an adverse event related to the study drugs you can contact to:

Dr _____

Contact phone _____

You will receive a card indicating that you are participating in this study. The card will include the name and phone number of the study doctor. Please have this card with you at all times, as long as you remain in the study.

For questions about your rights while taking part in this study, or if you feel that you have not been informed enough about your privacy rights about your health information, or you feel that the privacy of your health information has not been protected, you can contact your doctor.

INFORMED CONSENT FORM

I was informed about the study and had my first discussions with the study doctor or research staff about that information.

I have read and understand the information in this Patient Information Sheet/ Informed Consent document.

I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction.

I voluntarily agree to take part in this study. I do not give up any of my legal rights by signing this consent document.

I have been told that I will receive a signed and dated copy of this document.

I also agree to:

Blood samples not used on the analysis planned in the present study will be maintained in a research collection line for a maximum of 15 years. My samples can be used for future research in penile cancer for analysis not strictly related to the objectives of the current research, with prior approval of a Research Ethics Committee. Yes ☐ No ☐

Tissue samples not used on the analysis planned in the present study will be maintained in a research collection line, for a maximum of 15 years. My samples can be used for future research in penile cancer for analysis not strictly related to the objectives of the current research, with prior approval of a Research Ethics Committee. Yes ☐ No ☐

Samples not used beyond the storage period (up of 15 years) are transferred to a biobank (if box is unticked non-used samples will be destroyed). Yes ☐ No ☐

_____

Printed name of study participant

_____ _____

Signature of study participant Date of signature[1]

_____

Printed Name of the Person Conducting the Consent Discussion[2]

_____ _____

Signature of the Person Conducting the Consent Discussion Date of signature

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CONSENT FOR STUDY PARTICIPANT WHO CANNOT READ

Complete this section only if the Signature of an impartial witness is required. (It is required if the subject or subject's legally authorized representative cannot read.)

The study participant has indicated that he is unable to read. An impartial witness should be present during the entire consent discussion. One or more members of the study team read the consent document to the study participant, discussed it with the study participant and gave the study participant an opportunity to ask questions. The witness signs and personally dates the consent form. By doing so the witness attests that the consent information was accurately explained and that the subject apparently understood and informed consent was given freely.

_____

Printed name of impartial witness[3]

_____ _____

Signature of impartial witness Date of signature[1]

(1) *Subject / impartial witness must personally date their signature.*
(2) *The investigator, or a suitably qualified and trained person designated by the, must sign and date the consent document during the same interview when the subject signs the consent document.*
(3) *Impartial Witness: A person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the informed consent process if the subject cannot read, and who reads the informed consent and any other written information supplied to the subject. Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance.*