THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

IRB APPROVED
AS MODIFIED
2020-1046
Oct 03, 2022

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

TITLE: A Phase II Clinical Trial Evaluating the Efficacy and Safety of Sintilimab for Advanced Rare Cancers (SiARa Cancer Study) – Undifferentiated Pleomorphic Sarcoma (SiARa-UPS)

PROTOCOL NO.: 2020-1046
WCG IRB Protocol #20210148

SPONSOR: MD Anderson Cancer Center

INVESTIGATOR: Neeta Somaiah
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Houston, Texas 77030
United States

STUDY-RELATED PHONE NUMBER(S): Dr. Neeta Somaiah, at 713-792-3626
713-792-2121 (24 hours)

_____ _____
Participant's Name Medical Record Number

This consent and authorization form explains why this research study is being done and what your role will be if you choose to take part. You may choose not to take part in this study.

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

STUDY SUMMARY

The goal of this clinical research study is to learn if the investigational drug sintilimab can help to control malignant fibrous histiocytoma/undifferentiated pleomorphic sarcoma (MFH/UPS) and high-grade myxofibrosarcoma. The safety of this drug will also be studied.

This is an investigational study. Sintilimab is not FDA approved or commercially available. It is currently being used for research purposes only. The study doctor can explain how the study drug is designed to work.

The study drug may help to control the disease. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment.

You can read a full list of potential side effects below in the Possible Risks section of this consent.

You may continue taking the study drug as long as the doctor thinks it is in your best interest for a maximum of 24 months.

Sintilimab will be provided at no cost to you during this study.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive standard chemotherapy such as doxorubicin or pazopanib. You may choose to receive other investigational therapy, if available. You may choose not to have treatment for cancer at all. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

If you decide that you don't want any more active treatment, one of your options is called "comfort care." Comfort care includes pain medication and other support. It aims to maintain your comfort and dignity rather than cure disease. Usually this care can be provided at home.

If you think you might prefer comfort care, please discuss this with your family, friends and your doctor.

1. STUDY DETAILS

Screening Tests

Signing this consent form does not mean that you will be able to take part in this study. The following screening tests will be performed within 28 days before you will be enrolled and will help the doctor decide if you are eligible:

- You will have physical exam.
- You will have an EKG to check your heart function.
- Urine will be collected for routine tests.
- Blood (about 3 teaspoons) will be drawn for routine tests and to test for hepatitis B, hepatitis C, and HIV. State law requires positive test results for certain communicable diseases, including HIV, hepatitis, sexually transmitted

infections, and tuberculosis, to be reported to a local health agency. Some of the tests for this study must be reported when positive. The study doctor can discuss this with you.
- If you can become pregnant, blood (about ½ teaspoon) will be drawn for a pregnancy test. To take part in this study, you must not be pregnant.
- You will have a CT scan, MRI, or a PET/CT to check the status of your disease.
- If leftover tumor tissue is available, it will be collected for biomarker testing. Biomarkers are found in the blood/tissue and may be related to your reaction to the study drug. You will have a core needle biopsy of the tumor if there is no archival tissue available. To perform a core biopsy, under local anesthesia, a sample of tissue is removed using a hollow core needle that has a cutting edge.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other treatment options will be discussed with you.

Up to 27 participants will be enrolled in this study. All will take part at MD Anderson.

Study Drug Administration
Each cycle is 21 days.

You will receive sintilimab (200 mg) by vein over 30 to 60 minutes on Day 1 of each cycle for up to 2 years.

You will no longer be able to take the study drug if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

Study Visits
On Day 1 of Cycle 1:
- You will have a physical exam.
- You will questionnaires about your complete quality-of-life. They should take about 10 minutes to complete.
- Blood (about 4 teaspoons) will be drawn for routine tests.

On Day 1 of Cycle 2 and each cycle after that:
- You will have a physical exam.
- You will have an EKG to check your heart function.
- Blood (about 4 teaspoons) will be drawn for routine tests.
- You will complete the quality-of-life questionnaires.

On Day 1 of all even-numbered cycles starting with Cycle 2 (Cycles 2, 4, 6, and so on):
- If you can become pregnant, urine will be collected for pregnancy tests.
- Blood (about 1 teaspoons) will be drawn to test your thyroid function.

On Day 1 of Cycles 3, 5, and 7 and then every 3 cycles after that, you will have a CT scan, MRI, or PET/CT scan to check the status of the disease.

Biomarker Testing
Blood (about 4 tablespoons) will be drawn for biomarker testing at the following study visits.

- On Day 1 of Cycle 1, blood will be drawn 1 time before you receive the study drug.
- On Day 8 of Cycle 1, blood will be drawn 1 time.
- On Day 1 of Cycles 2 and 3, blood will be drawn 1 time before you receive the study drug.
- At the time the disease gets worse (the first time) and at your last dose of the study drug or the last imaging scan you have on study, blood will be drawn 1 time.

Pharmacokinetic (PK) and Antibody Testing
Blood (about 3 teaspoons each time) will be drawn for pharmacokinetic (PK) testing and/or antibody testing at the following study visits. PK testing measures the amount of study drug in the body at different time points. Antibodies are created by the immune system and may attack foreign cells or substances, such as the study drug.

- On Day 1 of Cycle 1, blood will be drawn within 1 hour before the dose and then 1 more time within 2-24 hours after the dose.
- On Day 8 of Cycle 1 (or any point within 5-11 days after the study drug on Day 1), blood will be drawn 1 time.
- On Day 1 of Cycles 2 and 4, blood will be drawn within 1 hour before you receive the study drug.
- Every 4 Cycles after starting with Cycle 7 (Cycles 7, 11, 15 and so on), blood will be drawn within 1 hour before you receive the study drug on Day 1.

End of Treatment Visit
Within 7(+/-) days after the last dose of the study drug, the following tests and procedures will be performed:

- You will have a physical exam.
- You will have an EKG to check your heart function.
- Blood (about 4 teaspoons) and urine will be collected for routine tests.
- You will have a CT scan, MRI, or a PET/CT to check the status of the disease.
- You will complete the quality-of-life questionnaires.
- If you can become pregnant, blood (about ½ teaspoon) will be drawn for a pregnancy test.

Follow-up Visits

Thirty (30) and 90 days after the last dose of the study drugs, the following tests and procedures will be performed:

Thirty (30) day visit:

- Blood (about 4 teaspoons) and urine will be collected for routine tests.
- You will be asked about any current signs and symptoms you are currently experiencing.
- You will be asked about any medications you may be taking.
- You will be asked about any anti-tumor treatments you may be receiving.
- You will complete questionnaires on the quality of your life.
- You will have an EKG to check your heart function.

Ninety (90) day visit:

- You will be asked about any symptoms you are currently having.
- You will be asked about and anti-tumor treatments you may be receiving.

Long-Term Follow Up

Every 2 months for up to 3 years after the last participant is enrolled on the study, until the study ends, or until you withdraw from the study, whichever comes first, the study staff will contact you by phone to ask how you are doing and to ask about any new treatments you are receiving. The phone call should last about 5 minutes.

Other Information

While on study, you cannot receive or take other investigational or standard-of-care anticancer therapies, medications that suppress the immune system, and herbal/natural remedies. Vaccines with live viruses should be avoided during the study and for 180 days after the last dose of study drugs. Vaccines with dead viruses should only be received 30 days before and after receiving a dose of the study drugs.

Talk to the study doctor before taking any prescription or over-the-counter medications during this study.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. These side effects will vary from person to person. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You should discuss these with the study doctor. You may also want to ask about other uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after treatment is stopped but in some cases, side effects may be serious, long-lasting, or permanent, and may even result in hospitalization and/or death.

Side effects will vary from person to person, and some may occur after you have stopped receiving treatment. Tell the study staff about any side effects you may have, even if you do not think they are related to the study drugs/procedures.

Sintilimab Side Effects

This is an early study of sintilimab in humans, so the side effects are not well known. Based on similar drugs, sintilimab may cause the following side effects:

• slow/irregular/fast heartbeat • high blood pressure • abnormal EKG • chest pain • heart failure • heart inflammation • fever • dizziness • difficulty sleeping • nervous system damage • facial nerve disorder • weakness • fatigue • chills • hives • pain (joint/limb) • skin rash • eczema (skin inflammation) • dry skin • itching • patches of skin color loss • abnormal growth in the thyroid • enlarged thyroid gland with neck swelling • high hormone blood levels • decreased production of adrenal hormones (possible weakness and/or low blood pressure) • underactive thyroid	• overactive thyroid gland (possible weight loss, heart rate changes, and/or sweating) • inflammation of the thyroid gland (possible tenderness in the neck) • loss of appetite • weight loss or gain • mouth blisters/sores • vomiting/nausea • diarrhea • constipation • digestive system bleeding • inflammation of intestine • high blood levels of uric acid (possible painful joints and/or kidney failure) • abnormal salts, minerals, and/or acids in the blood (possible weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental status, and/or seizure)	• high blood levels of fat (possible heart disease and/or stroke) • diabetes • high blood sugar (possible diabetes) • severe high blood sugar due to uncontrolled diabetes • low red blood cell count • abnormal liver tests (possible liver damage) • abnormal liver function • liver damage • abnormal kidney tests (possible kidney damage) • kidney damage and/or inflammation • blood in urine • lung inflammation (possible difficulty breathing) • cough • difficulty breathing • infection • infusion reaction (possible chills/hives) • allergic reaction

gland (possible weight gain, heart failure, and/or constipation)		

Sintilimab may cause tumor pseudoprogression. This occurs when the number and/or size of tumor(s) appear to increase in imaging scans. In reality, it is usually an inflammatory response with swelling that makes your tumors appear to be larger.

Sintilimab may cause low red blood cell counts. A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood transfusion.

Sintilimab works by boosting the immune system. This may cause unknown side effects resulting from your immune system attacking your organs. This may cause inflammation and inflammation-related side effects in any organ or tissue.

Pregnancy Related Risks
Taking part in this study can result in unknown risks to an unborn or breastfeeding baby, so you should not become pregnant, breastfeed a baby, or father a child while on this study. You must use birth control during the study if you are sexually active.

Birth Control Specifications: Women who are able to become pregnant must use at least 1 highly effective method of birth control (defined below) from Screening until 180 days after the last dose of the study drug. If you are male, you and your partner must use 1 highly effective method of birth control from Screening and until 180 days after the last dose of the study drug.

Single method (must use one)	**Double barrier (must use two)**
Intrauterine device	Condom
Birth control implant	Diaphragm/cervical cap with spermicide
	Hormonal birth controls including: Oral birth control, birth control patch, birth control ring

- Copper T intrauterine device (IUD)
- Levonorgestrel-releasing intrauterine system (IUS): e.g., Mirena®
- Implants: Etonogestrel-releasing implants: e.g. Implanon® or Norplant®
- Intravaginal: Ethinylestradiol/etonogestrel-releasing intravaginal devices: e.g. NuvaRing®
- Injection: Medroxyprogesterone injection: e.g. Depo-Provera®
- Combined Pill: Normal and low dose combined oral birth control pill
- Patch: Norelgestromin/ethinylestradiol-releasing transdermal system: e.g. Ortho Evra®
- Minipill: Progesterone based oral birth control pill using desogestrel: Cerazette®

Males: Tell the doctor right away if your partner becomes pregnant or suspects pregnancy.

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away.

Getting pregnant **will** result in your removal from this study.

Other Risks

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

Having **biopsies** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the biopsies. An allergic reaction to the anesthetic may occur. A scar may form at the biopsy site. The doctor will discuss any additional risks from the location and method of the biopsy.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair, Dr. Neeta Somaiah.

This study may involve unknown risks to the participants.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure #1: If you agree, you will have a tumor biopsy for biomarker testing on Day 1 of Cycle 3 (+/- 7 days).

Optional Procedure #2: If you agree, you will have a tumor biopsy for biomarker testing. This will be done at your last dose of study drug or at the last imaging scan you have during the study.

You do not have to agree to the optional procedures in order to take part in this study. There are no benefits to you for taking part in the optional procedures. Future patients may benefit from what is learned. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedure.

Optional Procedure Risks

Having **biopsies** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the biopsies. An allergic reaction to

the anesthetic may occur. A scar may form at the biopsy site. The doctor will discuss any additional risks from the location and method of the biopsy.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Circle your choice of "yes" or "no" for each of the following optional procedures:

Optional Procedure #1: Do you agree to have a biopsy on Day 1 of Cycle 3 for biomarker testing?

YES **NO**

Optional Procedure #2: Do you agree to have a biopsy at your last dose of the study drug or the last imaging scan you have on study?

YES **NO**

3. COSTS AND COMPENSATION

Compensation for Injury
If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson or Innovent Biologics Co., Ltd for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. If you are injured as a result of this study, you do not give up your right to pursue a claim through the legal system.

If you suffer a study-related injury, you may contact the Chair of the study, Dr. Neeta Somaiah, at 713-792-3626 or 713-792-2121 (24-hours) with any questions you may have. By signing this consent form, you are not giving up any of your legal rights.

Costs
Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

Compensation
Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

The sponsor may reimburse you for reasonable costs that are a direct result of your participation, such as travel expenses. You will need to provide receipts for your expenses to be eligible for reimbursement. This is an obligation between you and the sponsor. This is not a guarantee of reimbursement for all expenses, but a promise of good faith effort by the sponsor to provide some reimbursement of actual expenses incurred using the following guidelines.

All patients may be reimbursed for the following expenses in direct relation to study participation:

- You may receive up to maximum of $1,200.00 ($200.00/night for up to 6 nights) for hotel costs.
- You may receive up to maximum of $200.00 for mileage.
- You may receive up to maximum of $225.00 ($15.00/visit for up to 15 visits) for parking.
- You may receive up to maximum of $1,650.00 ($275.00/visit for up to 6 visits) for airfare.
- You may receive up to maximum of $600.00 ($40.00/visit for up to 15 visits) for meals.

The reimbursement process can be lengthy, sometimes taking 4 to 6 months to complete due to sponsor approval. If you have questions or concerns about your reimbursement, please contact the study staff.

You will receive reimbursement for participation via a Bank of America bank card. If your Bank of America bank card is lost or stolen, you must immediately report this to the Bank of America by calling 1-866-213-8564 and should call study staff to inform them as well. Please understand that Bank of America will charge $5.00 to replace the card and that fee is the participant's responsibility.

Additional Information

4. You may ask the study chair any questions you have about this study, if you have any questions, concerns, or complaints about the research, or if at any time you feel you have experienced a research-related injury or a reaction to the study drug. You may contact the study chair, Dr. Neeta Somaiah, at 713-792-3626, or 713-792-2121 (24-hours).

If you have questions about your rights as a research subject or if you have questions, concerns, or complaints about the research, you may contact:

WCG IRB
Telephone: 855-818-2289
E-mail: researchquestions@wcgirb.com

WCG IRB is a group of people who perform independent review of research.

WCG IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WCG IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits to which you are otherwise entitled.

   If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, Innovent Biologics Co., Ltd, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or WCG IRB.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

9. This study is supported by: Innovent Biologics Co., Ltd.

10. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s). If you have any questions about this, you may call WCG IRB at 855-818-2289.

11. The MD Anderson Conflict of Interest (COI) policy states that MD Anderson employees may not serve as the study chair or co-chair on a research study if they have received funds that are greater than the amount allowed by the policy or own stock in the sponsoring or supporting companies.

The COI policy and the IRB require that you be told about financial relationships that the study investigators may have with the study sponsor(s).

The MD Anderson Institutional Conflict of Interest policy requires that you be told about financial relationships that MD Anderson Institutional Decision Makers may have with the study sponsor(s) and significant financial relationships that MD Anderson may have with the study sponsor(s).

At this time, no financial relationships with the study sponsor(s) have been disclosed by any of the study investigators or Institutional Decision Makers.

There is a significant financial relationship between MD Anderson and Innovent Biologics Co., Ltd. This relationship has been identified as a financial conflict of interest.

The results of this study may result in a financial benefit for MD Anderson.

MD Anderson has taken steps to manage this financial conflict of interest. The plan to manage the conflict has been approved by the Executive Vice Chancellor for Health Affairs for The University of Texas System.

This financial conflict of interest may affect your willingness to take part in this study. If you have any questions or concerns related to MD Anderson's significant financial relationship with Innovent Biologics Co., Ltd, please call the MD Anderson Institutional Compliance Office at 713-745-6636. That office will provide you the contact information for a non-MD Anderson ethicist who can assist with your questions and concerns. In the event, a non-MD Anderson ethicist is not available, an MD Anderson ethicist will contact you to assist with your questions and concerns.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and Innovent Biologics Co., Ltd and/or shared with other researchers and/or institutions for use in future research.

Samples

Samples (such as blood and/or tissue) are being collected from you as part of this study. Researchers at MD Anderson may use any leftover samples that are stored at MD Anderson in future research. Leftover samples stored by Innovent Biologics Co., Ltd may be used in future research.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research samples. If all identifying

information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

Genetic Research
Research samples collected from you as part of this study will be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you.

Authorization for Use and Disclosure of Protected Health Information:

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Innovent Biologics Co., Ltd (and/or any future sponsors of the study)
   - The EVC and the Office of General Counsel for The University of Texas
   - Any future licensees of the study technology and an External Data Safety and Monitoring Board
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - WCG IRB
   - A non- MD Anderson ethicist
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it. If the results of this research are published, you will not be identified.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants. If the results of this study are made public, information that identifies you will not be used. You have the right to review and copy your health information. However, your access to this information may be delayed until the study is complete.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI and it may be re-disclosed.

The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

D. 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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed and dated copy of this consent document.

SIGNATURE OF PARTICIPANT DATE

PRINTED NAME OF PARTICIPANT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

PERSON OBTAINING CONSENT DATE

PRINTED NAME OF PERSON OBTAINING CONSENT