

UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

ViiV Healthcare A4001067, Amendment 3, dated November 29, 2010

**An International, Multicenter, Prospective Observational Study of the Safety of Maraviroc used with Optimized Background Therapy in Treatment-Experienced HIV-1 Infected Patients**

**CONSENT FORM & HIPAA Authorization TO PARTICIPATE IN A Non Interventional RESEARCH STUDY**

**Your contacts at the Hospital of the University of Pennsylvania, Philadelphia for this study are:**

Principal Investigator:	Pablo Tebas, MD	(215) 349-8092
Investigator:	Ian Frank, MD	(215) 349-8092
Coordinators:	Joseph Quinn, RN	(215) 349-8092
	Deborah Kim, RPh	(215) 349-8092
	Emily Stumm, BS	(215) 349-8092

24 Hour Emergency Number (215) 662-6059 Ask for the Immunodeficiency Program Doctor on call

**NATURE AND PURPOSE OF STUDY**

This form contains a full explanation of the study you are being invited to take part in and a place for you to sign if you decide to take part. ViiV Healthcare is sponsoring a study to assess the safety of a drug called maraviroc. Maraviroc has been approved by the U.S. Food and Drug Administration (FDA) under the name Selzentry and has been approved by Health Authorities in the European Union (EU) under the name Celsentri. This study was reviewed and received written favorable opinion/approval from the University of Pennsylvania's Institutional Review Board.

HIV infects and destroys cells of the immune system. In order for HIV to cause infection it needs to get into the cells. HIV uses either of two sites on the surface of the cell to enter. Some people have HIV that use one on these sites, and some people have mixed groups of HIV virus that use both sites at the same time. Maraviroc prevents the HIV from entering the cell by blocking only one of these sites. The scientific name for this site is (R5) HIV-1. Thus, maraviroc is prescribed to patients infected only with HIV which uses a specific site to enter the cell. Before you may be prescribed maraviroc, it is needed to determine what site your HIV uses to enter cells.

In this study, the safety of maraviroc, its effects on HIV-1 infection, and how well people tolerate it will be evaluated. You are being asked to participate in this study because you have HIV and based on your medical history your physician thinks that maraviroc may be used to treat your HIV infection along with other drugs.

Because maraviroc has been approved by the FDA, your physician may prescribe maraviroc for you as part of your standard medical treatment even if you do not participate in this study. You will also have the option of continuing to receive maraviroc even after your participation in this study is complete.

Not all of the people who participate in this study will receive maraviroc. Those who do not receive maraviroc will serve as a comparison group in the study. The opportunity to participate in the study will not affect your physician's decision whether or not to prescribe maraviroc.

In June 2010, ViiV Healthcare became the Sponsor for all research studies evaluating maraviroc, including this one. ViiV Healthcare is a global company that specializes in treatments for HIV and AIDS.

As the Sponsor, ViiV takes overall responsibility for the conduct of this research study and the safety of maraviroc. Pfizer will continue to manage this research study on ViiV's behalf.

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The change in Sponsor will not affect the treatment you are receiving or your medical care.

If you have any concerns or questions about the change in Sponsor, please discuss your concerns with the study team.

**EXPECTED DURATION OF THE STUDY AND NUMBER OF SUBJECTS EXPECTED TO PARTICIPATE**

There will be approximately 3000 people in this study. Each patient will be in the study for about 5 years. This study is being run at about 300 sites in multiple countries. About 10-20 subjects are expected to participate at the University of Pennsylvania.

**EXPLANATION OF PROCEDURES TO BE FOLLOWED**

**A. PROCEDURES OR THERAPY**

If you agree to participate, at the beginning of the study you will be given an HIV tropism assay (a type of blood test) to determine whether or not you have only R5-HIV-1, against which maraviroc is effective. This test will involve taking a sample of blood, which will be drawn as part of your routine medical management. The amount of blood needed for this test is 10 mL (milliliters), which is approximately 2 teaspoons.

If you do not have only (R5) HIV-1, you will remain eligible to enroll in the study but if you do enroll, you will not be prescribed maraviroc. If you do have (R5) HIV-1, your physician will decide whether maraviroc is the right treatment choice for you. The opportunity for you to participate in the study will not influence your physician's decision whether or not to prescribe maraviroc. All patients enrolled in this study will be treated with an optimized background antiviral therapy (OBT) regimen that includes antiviral drugs that are standard in the treatment of HIV. Your physician / practitioner will prescribe the combination of drugs that (s)he determines as best for you.

After you qualify for the study, a doctor will interview you and look through your medical records to get the following information:

- Birth date, sex, and race/ethnicity
- Height, weight, blood pressure, and general medical history including start and stop dates for past and current medications
- Risk behaviors for HIV exposure, duration of HIV infection, diagnosis date and type of AIDS-defining events
- Laboratory results from your most recent blood tests, including cholesterol, triglycerides, liver enzymes, alanine transaminase, aspartate transaminase, bilirubin, hepatitis B & C serology, CD4+ T lymphocyte cell counts, levels of HIV-1 RNA, and HCV RNA
- Result from the screening HIV tropism assay.

All visits and laboratory tests involved in this study are part of your standard HIV treatment. You will continue to see your doctor as you would were you not participating in the study. This means that you will likely be asked to visit your doctor 2 to 4 weeks after starting treatment and that you will be asked to return to the doctor for follow-up visits approximately 8 weeks and 12 weeks after starting treatment. After this, you will be asked to continue visiting the doctor approximately every 12 to 16 weeks, which is typical in HIV treatment. Your doctor will determine when a visit is necessary, as (s)he usually does.

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**B. FOLLOW-UP**

If you do not see the doctor during any 6-month period while you are enrolled in this study, the study doctor or study staff will need to try to contact you in order to collect relevant information to determine if you are still alive. In order to do this, the study staff will need you to give them the following:

- Contact information for your primary care physician
- Contact information for at least one alternate contact person who can be asked about your whereabouts and survival status
- Your social security number or other national identification number or national medical health insurance number (as allowed by law) in order to verify your survival status and determine if you developed any type of cancer by searching national or state vital status and cancer registries. This number may be used for up to 5 years following the end of this study by your physician or study staff for these purposes only.

Information about your health and treatment will be collected for at least 5 years. This information will come from your usual doctor visits and medical history as well as any tests that are conducted as part of your standard care. Information may also be obtained from other health care providers, clinics or hospitals where you may receive medical care during your participation in this study. Based on the results of this study, information about your health and treatment may need to be collected for more than 5 years.

There are other treatments for HIV. They include drugs that are approved and drugs that are not approved, but are available through other studies. The study doctor will discuss with you the good points and bad points of the other treatments for HIV and together with you will decide what the best option is for you.

**STUDY RESTRICTIONS/SUBJECT RESPONSIBILITIES**

Maraviroc

If maraviroc is prescribed, you will obtain it as you would any other medication prescribed by your doctor. It should be taken according to the product labeling and your doctor's instructions. You may be asked to bring unused maraviroc tablets to each study visit. The anti-HIV drugs used for your background standard treatment should be taken according to your doctor's instructions and product labeling. *It is very important that you stick to your dosing schedule and report any side effects to your study doctor or study staff. Do not change doses or stop medications before you speak to study personnel.*

Standard HIV Drugs

You will obtain your medications as you would any other medications prescribed by your doctor. These should be taken according to the product labeling and your doctor's instruction.

Risks of Maraviroc vs. Standard of Care

There is no greater risk for you to take your new therapy and be on the study. The decision to prescribe Maraviroc will be based on the laboratory tests that your doctor will do as part of standard of care. You will see your doctor and have the same evaluations as standard of care if you participate in the study.

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Other Therapies

While you are on this study, you must tell your doctor of all medications you are using. This includes "over-the-counter" medicines, vitamins, herbal remedies and recreational drugs. In patients that take lipid-lowering drugs, maraviroc may increase the risk of rhabdomyolysis (breakdown of muscle fibers resulting in the release of muscle fiber contents (myoglobin) into the bloodstream). St. John's Wort can affect the effectiveness of some of your HIV medications and should not be taken during the study period. There may be other treatments or medicines that may need to be added to the list of agents that should not be taken during the course of the study. You will be informed of these by your study doctor. If you are taking certain other medicines, your doctor may adjust your dosage of maraviroc or may tell you to stop taking maraviroc.

Pregnancy/Breastfeeding

We do not know if the drug may have bad effects on an unborn baby. It is therefore **VERY IMPORTANT** that **YOU DO NOT TAKE PART** in this study if you are pregnant, plan to become pregnant within at least 1 month of the end of the study, or are breast-feeding. Because the effects of maraviroc on sperm are not fully known at this time, men should use a condom to decrease the chances of pregnancy as well as of spreading HIV.

Side Effects

It is your responsibility to report to the study doctor or study staff all changes in your physical or mental condition during the study. If you become ill and need to take any medicine, please contact the study doctor right away. You will be told what treatment may be acceptable for you to take. Or, you may be advised to stop taking the study drug for a while or to withdraw from the study, if your study doctor feels that is needed.

**Tell a study doctor immediately if you have a side effect, an injury, any symptom or complaint or pregnancy.**

Private Medical Insurance

If you have private medical insurance, before you agree to take part in this study, you should check with your insurance company. Make sure that taking part in this study will not affect your medical insurance.

**POSSIBLE SIDE EFFECTS, RISKS, AND DISCOMFORTS**

Many of the risks associated with maraviroc are known. However, there may be rare and unknown risks, some of which may be life-threatening. Therefore, problems and side effects not listed in this section and not expected at this time could occur. You will be notified if new side effects of maraviroc become known during the study.

In patients that take lipid-lowering drugs, maraviroc may increase the risk of rhabdomyolysis. Allergic reaction to maraviroc is also possible. Therefore, it is important that you report **all** symptoms and side effects that you experience as soon as they occur, whether or not you think they are caused by maraviroc. Also, maraviroc contains soya lecithin and should not be used by people that are hypersensitive to peanut or soya.

You understand that your HIV symptoms may not be controlled by the treatments used in this study or may even worsen. You will be told of any changes in the way the study is done. You will be informed as

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soon as possible of any new findings relevant to this study. This information may affect your decision about continuing in the study.

**A. SIDE EFFECTS**

The side effects that occur in patients receiving maraviroc more frequently than in patients receiving only OBT include: cough, fever, upper respiratory tract infections, rash, musculoskeletal symptoms, stomach pain, and dizziness. Additional side effects may include: diarrhea, swelling, influenza, esophageal candidiasis, sleep disorders, stuffy or runny nose, and urinary abnormalities. Most side effects reported with maraviroc are mild to moderate in severity and do not cause patients to stop taking the drug. Rare, but potentially serious, side effects may include cardiac disorders, certain infections, and certain cancers. However, there is no proof that these rare side effects are specifically caused by maraviroc.

Liver problems (liver toxicity) have happened in patients taking maraviroc. An allergic reaction may happen before liver problems occur. The FDA has placed a “**black box**” (important revision) warning on the prescribing information for maraviroc to inform patients of the potential for liver problems. You should stop taking maraviroc and call your doctor immediately if you experience the following symptoms: an itchy rash on your body, yellow skin or eyes, dark (tea-colored) urine, vomiting and/or upper right stomach area pain. You should see your doctor right away, but continue taking maraviroc, if you experience nausea, fever, flu-like symptoms, or fatigue.

More information on the side effects and potential risks of maraviroc is listed in the prescribing information for maraviroc, which is provided when prescriptions for maraviroc are filled

**B. CHILDBEARING POTENTIAL**

**WOMEN**

If you become pregnant, or if you think you are pregnant, tell the study doctor immediately. There could be risks to an unborn child in this study. If you become pregnant during the study, you may be discontinued from study participation for safety reasons. If you become pregnant within 28 days after you have stopped taking maraviroc, we ask that you contact your study doctor for safety monitoring. In either case, please make your obstetrician aware of your study participation. Your study doctor will ask that you, or your obstetrician, provide updates on the progress of your pregnancy and its outcome. The study doctor will make this information available to the study sponsor for safety monitoring follow-up.

**MEN**

If your spouse or partner thinks she is pregnant during the study or within 28 days after you have stopped taking maraviroc, tell your study doctor immediately. If your partner becomes pregnant, she will be asked to sign a release of information form to allow your study doctor to contact her obstetrician to collect updates on the progress of the pregnancy and its outcome. The study doctor will make this information available to the study sponsor for safety monitoring follow-up.

**C. DISCOMFORTS**

Drawing blood for the screening HIV-tropism assay may cause pain, bruising, lightheadedness, and on rare occasion, infections.

**ALTERNATIVES**

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Your alternative is not to be in the study. You can get maraviroc without being in this study. There are other treatments for HIV. They include drugs that are approved and drugs that are not approved, but are available through other studies. The study doctor will discuss with you the good points and bad points of the other treatments for HIV and together with you will decide what the best option is for you.

**COSTS**

The cost of the initial HIV-tropism assay will be covered by ViiV Healthcare. All treatments and procedures conducted during this study are considered part of standard care and may or may not be covered by third party payers (such as insurance companies). ViiV Healthcare will not pay for any treatments or procedures that you may receive during your participation in this study, including maraviroc, except for any that are required to treat a research injury.

**PAYMENT FOR PARTICIPATION**

You will get a total of up to \$500.00 if you finish the whole study. If you do not finish the whole study, you will get \$25 for each study visit you finish, including the screening visit(s).

**COMPENSATION FOR INJURY**

ViiV Healthcare will cover the costs of this treatment. A research injury is any physical injury or illness caused by your participation in the study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not a research injury. Because maraviroc is being used in this study as standard medical treatment for your condition and participation in the study will not influence the decision to prescribe maraviroc, an adverse reaction to maraviroc will not be considered a research injury. Payment for such things as lost wages, expenses other than medical care, or pain and suffering is not available. To help avoid injury, it is very important to follow all study directions. You are not giving up any of your legal rights by signing this form.

There is no other compensation available from the University of Pennsylvania.

**POSSIBLE BENEFITS OF THE STUDY**

You may not receive a direct benefit from this study, however, other patients may benefit from the information learned from the study.

**INVESTIGATOR COMPENSATION**

The investigator or his/her institution is being compensated by ViiV Healthcare for his/her participation in this study.

**REMOVAL FROM THE STUDY**

The study doctor or ViiV Healthcare may decide to take you out of the study if:

- a. You do not follow the directions of the study doctor
- b. You develop a serious illness that is not related to taking part in the study

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- c. The study doctor decides that the study is not in your best interest
- d. ViiV Healthcare, the responsible regulatory authority, or Institutional Review Board/Independent Ethics Committee (IRB/IEC) decides to stop the study
- e. You become pregnant, intend to become pregnant, or are nursing a child during this study.

If you are instructed by the study doctor to stop taking maraviroc, or if you stop taking maraviroc for any other reason, you will still be followed as a study participant for a total of five years from your enrollment in the study, unless you withdraw your consent to participate in this study.

**RIGHT TO WITHDRAW FROM THIS STUDY**

Taking part in this study is up to you. You may choose not to take part or you may leave the study at any time. Choosing not to take part or leaving the study will not result in any penalty. You will not lose any benefits to which you are otherwise entitled. Your decision will not affect your access to medical care in the future. You may decide to stop taking maraviroc, but continue participating in the study. In this case, you will continue to make follow-up medical visits as instructed by your doctor.

**CONFIDENTIALITY**

**What personal health information is collected and used in this study and might also be disclosed?**

The following personal health information will be collected, used for research, and may be disclosed during your involvement with this research study:

- Name, address, telephone number, date of birth
- Social security number (for W-9 so you can receive payments)
- Personal and family medical history, including mental health records
- Current and past medications or therapies
- Information from a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature
- Results of tests you will undergo during this research study : HIV Tropism assay, HIV/STD/hepatitis test(s), results of your drug/alcohol test(s)/use/treatment

**Why is your personal contact and health information being used?**

Your personal contact information is important for the research team to contact you during the study. Your personal health information and results of tests and procedures are being collected as part of this research study. In some situations, your personal health information might be used to help guide your medical treatment.

**Which of our personnel may use or disclose your personal health information?**

The following individuals may use or disclose your personal health information for this research study:

- The Principal Investigator and the Investigator's study team
- Authorized members of the workforce of the UPHS and the School of Medicine, and University of Pennsylvania support offices, who may need to access your information in the performance of their duties (for example: for research oversight and monitoring, to provide treatment, to manage accounting or billing matters, etc.).

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**Who, outside of UPHS and the School of Medicine, might receive your personal health information?**  
As part of the study, the Principal Investigator, the study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures. This information may be disclosed to those listed below:

Individuals or organizations responsible for administering the study:

Your personal data generated during this study may be passed on to the appropriate authorities, to the Sponsor, ViiV Healthcare, Inc., other researchers, and to people or companies working on behalf of or owned by the Sponsor. However, information that directly identifies you, such as your name and address, will not be transmitted. The Sponsor may use the collected information to determine if the study drug is safe and effective, to compare the study drug to other drugs, for regulatory activities and for future research activities that are unanticipated at this time.

Regulatory and safety oversight organizations

- The Food and Drug Administration
- The Office of Human Research Protections
- The study Data and Safety Monitoring Board
- Other Regulatory agencies outside the US

Once your personal health information is disclosed to others outside of UPHS or the School of Medicine, it may no longer be covered by federal privacy protection regulations. Data are reported to the sponsor on Case Report Forms that identify you by your unique study number and not your name, date of birth or medical record number. Information regarding your health, such as side effects of the study vaccine you experience will be reported only by code number. All samples collected for analysis will be labeled with your study number, visit number and date of your visit.

In addition to using it for this study, the sponsor may reanalyze the study data at a later date or combine your information with information from other studies for research purposes not directly related to this study.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

**How long may UPHS and the School of Medicine be able to use or disclose your personal health information?**

Your authorization for use of your personal health information for this specific study will expire in 50 years.

Your information may be held in a research repository (database). However, UPHS and the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization to do so



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- The University of Pennsylvania's Institutional Review Board grants permission after ensuring that appropriate privacy safeguards are in place
- As permitted by law

**Will you be able to access your records?**

During your participation in this study, you might not be able to access some or all of your medical records. For example, access to portions of your medical records may be denied in studies where your knowledge of study results included in such records could affect the reliability of the study. You will have access to your medical record information when the study is over or earlier, if possible. The Principal Investigator is not required to release research information to you that is not part of your medical record.

**Can you change your mind?**

Yes, at any time you may withdraw your approval to allow the use and disclosure of your personal health information as described here. You must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, your personal health information that was collected before we received your written request may still be used and disclosed, as necessary for the study. If you withdraw your permission to use your personal health information, you will also be withdrawn from the research study.

If you withdraw your permission to use any blood or tissue obtained for the study, the Principal Investigator will ensure that these specimens are destroyed or will ensure that any information that could identify you is removed from these specimens.

Indicate your agreement to the use and sharing of your records by checking the box below and signing:

- ☐ I agree to the use and sharing of my medical records and health information related to this study as described above.
- ☐ I also agree to the use and sharing of the following records as described above:
- ☐ HIV/STD/hepatitis test results
  - ☐ Drug/alcohol test/use/treatment records
  - ☐ Mental health records

\_\_\_\_\_  
Signature of Participant or Legal Representative

\_\_\_\_\_  
Date

**What is an Electronic Medical Record?**

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

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If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any results of procedures performed as part of this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Results of research procedures performed as part of your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

**CONTACT INFORMATION**

For questions about this study or a research-related injury, contact:

- Pablo Tebas, MD (215-349-8092)
- Clinical Trials Unit (215-349-8092)

For questions about your rights as a research subject, contact:

- Director of Regulatory Affairs at the University of Pennsylvania by phoning (215) 898-2614

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania Health System and the School of Medicine to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania Health System and the School of Medicine to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent/HIPAA Authorization form ( which 12 pages) will be given to you. You will also be given the University of Pennsylvania Health System and School of Medicine's Notice of Privacy Practices that contains more information about the privacy of your health information.

This Consent Form contains important information to help you decide if you want to be in this study. If you have questions that are not answered in this form, please ask one of the study staff.

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SIGNATURES:

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\_\_\_\_\_  
Printed name of study participant

\_\_\_\_\_  
Signature of study participant

\_\_\_\_\_  
Date of signature

\_\_\_\_\_  
Time (if needed)\*

\_\_\_\_\_  
Printed name of legally authorized representative  
& relationship

\_\_\_\_\_  
Signature of legally authorized representative

\_\_\_\_\_  
Date of signature

\_\_\_\_\_  
Time (if needed)\*

**PERSON OBTAINING CONSENT**

\_\_\_\_\_  
Printed Name of the Person Conducting the  
Consent Discussion

\_\_\_\_\_  
Signature of the Person Conducting the  
Consent Discussion <sup>†</sup>

\_\_\_\_\_  
Date of signature

\_\_\_\_\_  
Time (if needed)\*

**CONSENT FOR STUDY PARTICIPANT WHO CANNOT READ**

The study participant has indicated that he/she is unable to read. One or more members of the study team read the Addendum to the consent document to the study participant, discussed it with the study participant, and gave the study participant an opportunity to ask questions.

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\_\_\_\_\_  
Printed name of impartial witness <sup>†</sup>

\_\_\_\_\_  
Signature of impartial witness

\_\_\_\_\_  
Date of signature

\_\_\_\_\_  
Time (if needed)\*

\* Time is needed only if information was provided and consent is given on the same day, or if consent is given and any study-specific activities will be performed on the same day.

<sup>†</sup>The investigator, or a suitably qualified and trained person designated by the investigator to conduct the informed consent process, must sign and date the form at the same time as the subject.

<sup>†</sup> 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 or the subject's legally acceptable representative 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