INFORMED CONSENT COVER PAGE

A Prospective Single-Arm Multicenter StuDy of the BarE TEmporary SPur StEnt System foR the tREatment of Vascular lesions located in the infrapoplitEal Arteries beLow the knee (DEEPER REVEAL)

Protocol ID: CP-007

NCT Identification Number: NCT05358353

Date of Document: 06 January 2023

IRB Approved Template
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AS MODIFIED

INFORMED CONSENT TO TAKE PART IN A CLINICAL RESEACH STUDY

TITLE:	A Prospective Single-Arm Multicenter StuDy of the BarE TEmporary SPur StEnt System foR the tREatment of Vascular lesions located in the infrapoplitEal Arteries beLow the knee (DEEPER REVEAL)
PROTOCOL NO.:	CP-007 WCG IRB Protocol #20224902
SPONSOR:	Reflow Medical, Inc.
INVESTIGATOR:	Name Address City, State Zip Country
STUDY-RELATED PHONE NUMBER(S):	Phone Number Phone Number (24 hours) [24 hour number is required]

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

This study may enroll subjects who do not have the legal capacity to provide informed consent. The person providing consent for the subject may be a legal guardian or legally authorized representative (LAR). This person will sign this form to give permission or consent for the subject to take part in the study. Under these circumstances the terms “you” and “your” in this form refer to the subject undergoing the described procedures and not to the person providing consent for the subject.

This consent form may contain words that you do not understand. Please ask the doctor or the research staff to explain any words or information that you do not clearly understand.

You should keep a copy of this form. If you have any questions or problems during the study, please call the phone number(s) above.

WHAT YOU SHOULD KNOW ABOUT RESEARCH STUDIES

- You are being asked to be in a research study.
- You are being asked to authorize the release of your images (Angiogram [procedure], ultrasound, wound photographs, CT scan, and/or MRA) to employees of a company that is sponsoring a clinical research study (Sponsor).
- This consent form explains the research study.
- Please read it carefully and ask questions about anything you do not understand.
- If you do not have questions now, you may ask later.
- If this study relates to a health problem you have, we will explain what other treatment could be given outside the research. You should understand those options before you sign this form.

PURPOSE OF RESEARCH

You are invited to participate in a research study of an investigational Reflow Medical Bare Temporary Spur Stent System. We hope to learn how safe and effective the Bare Temporary Spur Stent System is when used in patients who have blocked arteries in their lower limbs.

You were selected as a possible participant in this study because your doctor has determined that you have Critical Limb Ischemia (CLI), a form of Peripheral Arterial Disease (PAD) in which an artery (blood vessel) in your lower leg (calf) may have become blocked. To improve blood flow to your lower leg, your doctor would like open up this blockage using the Bare Temporary Spur Stent System.

The Bare Temporary Spur Stent System will be used in every study participant who meets all the eligibility criteria for the study. The final decision to use the device will be made by your doctor after arterial access is successful.

This research study is looking to enroll up to 130 people in the United States and Europe with PAD/CLI for participation. [Site] expects to enroll [Site Enrollment] research study participants.

If you decide to terminate your participation in this study, you should notify [name] at [telephone number].

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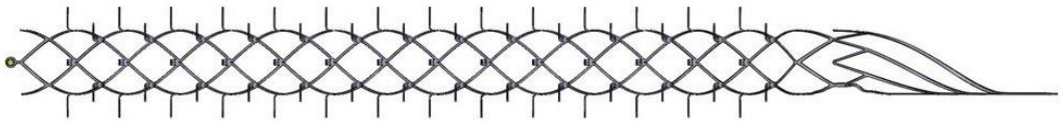
DEVICE DESCRIPTION



Pictured: The Bare Temporary Spur Stent System Stent

The study device that will be used in this study is called the Bare Temporary Spur Stent System. It is intended to be used for treatment of Critical Limb Ischemia (CLI). [redacted]

[redacted]

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

DURATION OF STUDY INVOLVEMENT

Your participation in this study will take approximately 1 year. This includes the Bare Temporary Spur Stent System procedure and periodic follow up visits with the doctor and his research staff through 1 year.

PROCEDURES

SCREENING:
Your Doctor will assess your overall health condition and medical history to see if you meet all the conditions for entry into the study. If your Doctor decides that you may be a candidate for the study you will be invited to participate. After you have read through and understand this information, and if you agree to participate, you will be asked to sign the consent form with the Doctor or the doctor's representative present. [redacted]

In the instance that you decide not to be involved in the study prior to the procedure, you would continue to be treated according to the standard of care for your condition.

If you agree to participate in this study, information about your procedure and your health will be collected for one year following your procedure. This information will be combined with information collected from other patients to help evaluate the clinical outcomes for this device. It will help evaluate the best way to use the device in the future.

PROCEDURE:
The procedure is very similar to the standard treatment (balloon angioplasty) you would receive for the treatment of a narrowed or blocked blood vessel in your leg. [redacted]

[redacted]

If your doctor thinks your narrowing or blockage is not suitable for the study, you will be treated with another procedure (see Alternative Treatments), and at this point you will not be enrolled into the study.

[redacted]

STUDY PROCEDURE

[redacted]

Before, during and after the procedure, your heart rate, blood pressure and overall condition will be monitored for signs of any adverse effects from the procedure or use of the study devices.

Representatives from the company that manufactures the Bare Temporary Spur Stent System may be present during the procedure and may take photographs and/or video tape the procedure for review by employees of the company and/or for future training purposes. If photographs or a video is taken, the company will block / blur out any information or pictures that could identify you.

☐ Yes, I agree to allow photographs and/or videotaping during my procedure as long as my identity is not known.
Subject Initials: _____

☐ No, I do not want photographs and/or videotaping during my procedure.
Subject Initials: _____

Once your doctor finishes the balloon angioplasty procedure all the tubes will be removed from your groin; this will be the end of the procedure.

After the procedure and before you leave the hospital or clinic, you will be seen by the doctor and assessed for any new problems.

As part of the normal standard of care for someone who has undergone a balloon angioplasty, your Doctor will ask you to take two blood thinning medications called Clopidogrel and Aspirin. Aspirin and Clopidogrel are routinely given after balloon angioplasty procedure to prevent blood from clotting. You may be asked to take Clopidogrel and Aspirin for at least 6 months; however, your doctor will discuss this with you.

Information on the risks of Clopidogrel and Aspirin is listed under the heading of POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES later in this consent form.

Follow-up Visits:
After you leave the hospital, you will need to attend the following clinic visits so we can monitor your health. At each of these visits, data will be collected about your current health condition to determine if there have been any changes or side effects (adverse effects) to you. It is very important to both your care and to the study that you keep all of your follow-up appointments at the times specified. These visits closely follow the standard of care follow up for someone like yourself who has had an angioplasty. Please feel free to bring someone with you to the clinic appointments.

These are the assessments required and the time points they will be collected at:

Follow up Procedures

[redacted]

Your participation in the study will be complete after your **one year** follow-up visit. You may need other follow up that is outside this trial. If you have any symptoms, are seen by any other doctor or are hospitalized, it is important that you call the doctor or research coordinator as soon as possible so that important information can be collected.

The information collected during the follow up visits will also be provided to the sponsor of the study.

[redacted]

[redacted]

IMAGING RELEASE AUTHORIZATION

You are being asked to allow release of your images (for example, angiogram, ultrasound, and wound photographs) to the Sponsor or their representatives in order to determine if you are eligible to participate in the study.

Your CT, MRA, or angiogram images and ultrasound images previously obtained will be read and reviewed by the doctor and research staff. If the doctor thinks you may be a candidate for the clinical research study, they may send your images to the study Sponsor to confirm.

If it is determined you are a candidate for study participation, any imaging of the study artery obtained throughout the study (screening/baseline visit, the procedure and at every follow-up visit through the 12 month visit) will be shared with the Sponsor for research analysis purposes. All personally identifiable information to be collected with the CT, MRA, angiogram and ultrasound images will be held strictly confidential. Whenever possible, personal information such as your name or date of birth will be removed from these records before sharing them. Although every reasonable effort will be made to protect the confidentiality of your records, such protection cannot be guaranteed.

With respect to scientific studies of this nature, personal data and medical findings are anonymously listed concerning your identity. [redacted]

Medical personnel associated with the study; and

- The Food and Drug Administration (FDA) and other regulatory agencies both within the United States and in foreign countries.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the doctor and research staff.
- ***Take the prescribed antiplatelet medications as instructed. This is extremely important for the study.***
- Keep your study appointments. If it is necessary to miss an appointment, please contact the research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the doctor or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the doctor or research staff about any allergies to antiplatelet medications, X-ray contrast material or metal implants.
- Tell the doctor or research staff if you believe you might be pregnant.
- Ask questions as you think of them.
- Tell the doctor or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled and will not affect your ability to receive access to health care at [Institution].

If you decide to withdraw your consent to participate in this study, you should notify [Investigator] at [telephone number] or in writing and let him/her know that you are withdrawing from the study. His/her mailing address is [insert site address].

The Doctor may also withdraw you from the study without your consent for one or more of the following reasons:

- You have a bad side effect.
- The Doctor decides that continuing your participation could be harmful to you.
- The study is cancelled.
- Other administrative or medical reasons.

If you withdraw from the study, you will be asked to complete discontinuation assessments. You may choose not to complete these assessments and no new data about you will be collected for study purposes unless the data concerns an adverse event (a bad effect) related to the study. If such an adverse event occurs, your entire medical record may need to be reviewed. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

All reasonable efforts have been taken to minimize risk for your participation in this clinical study according to regulations. Although extensive preclinical testing and clinical research trials outside of the USA have been done with the study devices, there may be unknown side effects that cannot be predicted or foreseen.

There are standard risks associated with any procedure like this one, and your doctor will review these risks with you before the procedure.

As is the case of any procedures involving collection of blood, you may experience mild, temporary discomfort at the location where blood was drawn, and there is a chance that you could have some temporary bruising or infection as well.

Your doctor will be using contrast material (X-ray dye) to look at your leg arteries, which carries some risk of allergic reaction. You should tell your doctor if you have an allergy to contrast, iodine, or shellfish; or if you have impaired kidney function. Your doctor will access your leg arteries with a number of catheters and small wires during the procedure, including the study device. There are risks

associated with these types of devices and procedures including but not limited to:

- Access vessel occlusion (blockage)
- Amputation
- Aneurysm or pseudoaneurysm (weakening of the artery wall)
- Bleeding complications
- Death
- Device or deployment malfunction/failure
- Drug reactions to antiplatelet or contrast injection
- Fever without sign of infection
- Hypotension/hypertension (low or high blood pressure)
- Infection local or systemic including bacteremia or septicemia (infection throughout the body)
- Myocardial infarction (heart attack)
- Pain (insertion site, leg and/or foot)
- Renal insufficiency or failure secondary to contrast medium (kidney problems related to the dye use)
- Shock
- Stenosis or occlusion (narrowing or blockage of the blood vessel)
- Stroke or transient ischemic attack (mini-stroke)
- Thrombosis (blood clot in the artery)
- Vessel wall damage (dissection, perforation or rupture)
- Vessel spasm

The risks associated with dual antiplatelet therapy may include:

- Increased bleeding
- epistaxis (nose bleed)
- headaches
- pruritis (itching)
- bruising

[redacted]

WOMEN OF CHILDBEARING POTENTIAL

Being a part of this study while pregnant may expose the unborn child to significant risks; including those that may be unknown. Therefore, pregnant women and women who are nursing their babies will be excluded from the study. In addition, women of childbearing potential will be asked to use an acceptable form of birth control during study participation. Acceptable forms of birth control will be reviewed with you by your physician.

POTENTIAL BENEFITS

Since there is limited clinical experience with this device, there is no guaranteed clinical benefit to you for participating in the trial. It is possible that treatment with the Bare Temporary Spur Stent System may increase blood flow to your lower leg by opening up blockages. There may also be some benefit from more frequent follow up with your doctor because of the study follow up visits.

The results of this study and your response to the treatments and therapies may provide information that could help other patients with similar conditions in the future.

Additional procedures and/or vascular surgery may still be necessary if the Bare Temporary Spur Stent System is not successful in restoring blood flow to your lower leg.

NEW INFORMATION:

You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

ALTERNATIVE TREATMENTS

You do not have to participate in this clinical trial or receive the Reflow Medical Bare Temporary Spur Stent System to treat your blocked leg artery, as other options are available. Other options include, but are not limited to, open surgical repair, standard endovascular procedures (balloon angioplasty, atherectomy, or permanent stents), or choosing no treatment.

Your doctor will explain treatment alternatives and the potential benefits and roles of each. You will have an opportunity to ask questions and discuss all potential treatment options with your doctor.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, contact and tell the doctor at the phone number listed on page 1 of this consent form.

You will be told of any important new information that is learned during this research study, which might affect your condition or your willingness to continue participation in this study.

CLINICALTRIALS.GOV

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.

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law**.** However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain data or information on the safety and effectiveness of the Reflow Medical Bare Temporary Spur Stent System; the results will be provided to the Sponsor, the IRB, the Food and Drug Administration and other federal and regulatory agencies as required.

RECORD RETENTION

Your study records will be retained for a minimum of 2 years after the investigational device is approved. If the device is not approved, your study records will be retained for a minimum of 2 years after the completion of the

study. At that time, study information that can identify you will be removed from [Institution] study files and destroyed. Any research information in your medical record will be kept indefinitely.

FINANCIAL CONSIDERATIONS

Payment
You will not be paid to take part in this clinical trial. You may receive reimbursement for travel related costs to and from the hospital.

Costs
There are no additional costs incurred by patients participating in this study. Neither this hospital nor Reflow Medical, will pay for the costs of "standard-of-care" procedures, tests, visits, nor hospitalizations connected with this research. Your hospitalization, laboratory work and all follow-up visits will be considered part of your routine medical care and will be billed to you or your insurance company in the usual manner.

Sponsor
Reflow Medical, is providing financial support and/or material for this study.

COMPENSATION FOR RESEARCH RELATED INJURY

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. Despite all precautions, you may develop medical complications from participating in this study. If such complications happen, the doctor and the research study staff will help you in obtaining appropriate medical treatment. If you are injured or become ill from taking part in this study, the Study Site will provide medical treatment if you wish, but the Study Site will not pay for such care or provide you with financial compensation. In the event that you have an injury or illness that is directly caused by your participation in this study, care will be provided to you. If it is determined that the illness or injury is directly related to the study device, Reflow Medical, agrees to pay all reasonable and necessary medical expenses to treat such illness or injury. You will **not** be responsible for any of these costs. Medicare, Medicaid, Tricare or your insurance company will not be billed for these injuries.

The Study Site has not set aside any funds to pay for this care or compensate you if a mishap occurs.

Temporary pain or discomfort, known complications associated with other approved therapies or any required treatment related to the natural progression

of your pre-existing condition will not be considered a study device related injury or illness.

You do not waive any liability rights for making a claim through the legal system for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the doctor, [name and phone number of Principal Investigator]. You should also contact him/her at any time if you feel you have been hurt by being a part of this study.

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

If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Institutional Review Board (IRB) to speak to someone independent of the research team at 855-818-2289 or researchquestions@wcgirb.com.

STATEMENT OF CONSENT

Consent/assent instructions

- All subjects unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted
- If assent is obtained, have the person obtaining assent document assent on the consent form

I consent to take part in this research study. I agree to follow instructions from the doctor. This study and the information in this consent form have been explained to me. I have read (or someone has read to me) the information in this form, and I understand the information. I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. I have been told I that I have not given up any legal rights. I have been told who to contact if I have additional questions. I will receive a copy of this signed and dated consent form. I authorize the use and disclosure of my health information to the parties listed in this consent for the purposes described above.

I agree to voluntarily participate in this study.

My signature below indicates that I understand the information provided and I have decided to take part in this study.

Printed Name of Subject

Signature of Subject **Date**

I certify that I am the legally authorized representative of the subject named above. I am permitted under state law to sign this form on behalf of the subject.

Printed Name of Legally Authorized Representative (LAR)

Signature of Legally Authorized Representative **Date**

Legally Authorized Representative's relationship to subject

The information about the study was described to the subject/LAR in language he/she understood.

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent **Date**

- ❑ I have explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study.

OR

- ❑ The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

_____ _____
Signature of person obtaining assent Date

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

Printed Name of Impartial Witness

Signature of Impartial Witness **Date**

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

An impartial witness is:

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

AUTHORIZATION TO USE YOUR HEALTH INFORMATION FOR RESEARCH PURPOSES (HIPAA AUTHORIZATION)

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?
The purpose of this research study is to evaluate the safety and effectiveness of the Reflow Medical Bare Temporary Spur Stent System in the treatment of atherosclerotic lesions of the infrapopliteal arteries.

Do I have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study including receiving the Reflow Medical Bare Temporary Spur Stent System. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?
YES. If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: [name and phone number].

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

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

What Personal Information Will Be Obtained, Used or Disclosed?
The doctor and study staff will use and share your health information as part of this research study. This may include your name, address, telephone number or other facts that could identify the health information as yours.

Examples of the information that may be used are:

- Past and present medical records
- Research records
- Phone call records related to this research
- Records about your clinical study visits
- Physical exams, blood tests, imaging, and/or other test results
- Records about any investigational device you received

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Doctor [Investigator]
- Institutional Review Board (IRB)
- Research Staff

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- Reflow Medical (the company that is sponsoring this study, “Sponsor”), and its agents, including a Clinical Research Organization (representative hired by the Sponsor to manage the study), and a Core Central Imaging Lab (an imaging lab contracted by the sponsor to read and interpret imaging for all subjects).
- Independent Institutional Review Board (or hospital ethics committee)
- The U.S. Food and Drug Administration (FDA)
- Other regulatory agencies

Your information may be re-disclosed by the recipients described above if they are not required by law to protect the privacy of the information.

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the clinical research study. The Sponsor will analyze and evaluate the results of the clinical research study. In addition, persons associated with the Sponsor and its consultants will be visiting research sites in order to assure strict protocol compliance and will be reviewing your medical information for this purpose. A sponsor representative may be present during your procedure.

The information will be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the Sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed (shared).

Is my health information protected after it has been given to others?
Your health information may be further shared by the groups above. If shared by them, the information will no longer be covered by this Authorization and may no longer be protected by federal law. These groups are committed to keeping your health information confidential.

When will my authorization expire?
[Your agreement to the use of your information and to allow other parties to review your information has no expiration date,

OR

This permission will be good until [Date] required in CA, DE, IN, IL, WA, and WI].

May I review or copy the information obtained or created about me?
YES. 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.

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

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AUTHORIZATION

By signing this form, I allow the use or disclosure of my health information. I will receive a signed and dated copy of this Authorization.

Printed Name of Subject

Signature of Subject **Date**

I certify that I am the legally authorized representative of the subject named above. I am permitted under state law to sign this form on behalf of the subject.

Printed Name of Legally Authorized Representative (LAR)

Signature of Legally Authorized Representative **Date**

Legally Authorized Representative's relationship to subject

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

Printed Name of Impartial Witness

Signature of Impartial Witness **Date**

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

An impartial witness is:

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