

About this consent form

TITLE:	Multi-Parametric MRI Assessment of the Liver in the Dallas-Fort Worth Metroplex Population (Registry)
PROTOCOL NO:	EC-236
SPONSOR:	Perspectum Diagnostics
INVESTIGATOR:	Carlos Duncker, MD, PhD
REGISTRY-RELATED PHONE NUMBER(S):	[972-803-5501]
SUBJECT POPULATION:	Adult volunteers living in the DFW metroplex and willing to get an MRI scan for the assessment of their liver

We would like to invite you to take part in this registry. Before you decide whether or not to take part, it is important for you to understand why the registry is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish. The principal investigator will answer all questions that you have before you decide if you want to take part.

If you decide to take part in this registry, you must sign this form to show that you agree to take part. You must do this alongside a member of the registry team. We will give you a signed copy of this form to keep for your records.

Please read this form carefully. It tells you important information about a registry. A member of our registry team will also talk to you about taking part in this registry.

If there is anything that is not clear, or if you would like more information, please contact the registry team.

Detailed Information

The following information is to help you decide whether or not to take part in this registry.

Why is this registry being done?

Perspectum Diagnostics (PD) provides a Magnetic Resonance Imaging (MRI) technology for aiding in the diagnosis of liver disease. Its flagship product, LiverMultiScan, is a non-invasive technique based on MRI imaging that aids in quantifying the health of the liver in a simple 15-minute scan. It is a painless tool that can better identify patients with fatty liver and other liver diseases. LiverMultiScan has been successfully adopted worldwide for both clinical use and research use in clinical trials in the investigation of liver disease.

A large percentage of Americans are currently diagnosed with a fatty liver (NAFLD/NASH). The current standard of care for its diagnosis may include a liver biopsy – this is an invasive procedure that involves taking a small piece of tissue from your liver. Liver biopsy is currently regarded as the gold standard for assessing the health of the liver. However, it has potential complications and can be inaccurate and uncomfortable.

The purpose of this registry is to invite volunteers to get a free LiverMultiScan so that Perspectum Diagnostics can gain a better knowledge of the presence of liver disease in the DFW metroplex. Perspectum Diagnostics also wish to collect your contact information to contact you in the future about research studies that may be of interest to you.

Why have I been invited?

You have been invited to take part in this registry as you have agreed to get a LiverMultiScan performed at no cost to you. By signing this document, you agree to undergo an MRI scan and also give us permission to contact you in the future to discuss potential studies that may be of interest to you.

By signing this consent form, you also give us permission to share a copy of your LiverMultiScan report with a healthcare provider of your choice so that if the provider wishes to view it, or thinks it's beneficial, this report can be used as part of your clinical pathway. These reports may be shared by a designated member of the registry team with your healthcare provider.

The aim is to recruit 100 participants across the Dallas-Fort Worth Metroplex.

How many visits will I have to participate in to be a part of this registry?

There is only one visit. This will include signing the consent form and undergoing an MRI scan.

Participants will be scanned at one of the following participating locations. The scan will be arranged at the center convenient to you:

- Advanced Imaging Center - Touchstone Imaging located at 411 N. Washington Ave, Suite 1000, Dallas TX, 75246.
- Touchstone Imaging Southlake located at 925 E. Southlake Blvd Suite 220, Southlake TX, 76092

You are free to withdraw your consent from the registry at any time, in which case we will remove your contact information but retain your de-identified data.

Are there any possible disadvantages or risks from taking part?

Magnetic Resonance Imaging (MRI) does NOT use radiation. MRI scans are known to be very safe, low-risk procedures. If there are any reasons why you may not be suitable for Magnetic Resonance Imaging (MRI) such as having a pacemaker, metallic implants or fragments in your body, excessive

tattoos, a phobia of closed spaces (claustrophobia), or if you are pregnant you will not be able to take part in the study.

If there are no reasons that stop you from undergoing an MRI and you are still interested in taking part in the registry after reading this consent form, we will invite you to come in for your visit.

What will happen if I take part in this registry?

On the day of your appointment, you will be introduced to a member of the registry team who will explain the visit and answer any questions you may have. If you are happy to proceed, you will be asked to sign the registry consent form and undergo an MRI scan lasting approximately 15 minutes.

Prior to your MRI scan, we will:

1. Ensure that you are suitable to have an MRI scan;
2. Perform a scan of your liver using an MRI machine. The MRI scanner uses a strong magnetic field but does not use X-rays or any form of radiation. The scan lasts about 15 minutes. You will be asked to lie on a table which slides into the scanner. The scanner can be noisy, however we will provide earplugs and/or headphones. Some people may feel claustrophobic in the scanner and you could at any time ask us to stop the scan. You need to fast for 4 hours before your scan. If it is difficult to fast before the scan, please discuss this with your doctor so that you could be advised. After the scan is finished you can eat and drink as usual.

What are the possible benefits of taking part in this registry?

There is no anticipated benefit for you. However, this registry will allow us to use your contact details to contact you directly if we believe there are other studies that could benefit you and if you would be interested in participating in them. Also, it will help us to gain a better understanding about the presence of liver disease in the Dallas-Fort Worth Metroplex area.

Do I have to take part?

No – it is up to you to decide whether or not to take part. This is not a treatment study. It is totally voluntary. If you decide to take part, you are free to withdraw from the registry at any time without giving a reason. You may decide to not participate and withdraw at any time without any penalty or loss of benefits to which you are otherwise entitled.

What happens if anything unexpected is found?

The MRI scan and the images acquired are not a part of standard of care. Our scans are primarily for the purposes of the registry only, however if we find anything unusual, it would be appropriate for us to contact your clinical care doctor so that he/she can arrange ongoing care for you as needed.

Who can answer my questions about this registry?

You can talk to the principal investigator about any questions, concerns or complaints you have about this registry. Contact your registry doctor using the following contact details:

Name Carlos Duncker, MD, PhD
Contact Details carlos.duncker@perspectum.com

You can also contact a member of the registry team using the following details:

Name Amna Soomro, MB.BS
Contact Details amna.soomro@perspectum.com

This registry is being overseen by an Institutional Review Board (“IRB”). An IRB is a group of people who perform independent reviews. You may talk to them at (800) 562-4789, help@wirb.com if:

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

How may we use and share your health information for other research?

The data collected from this registry may be used in other research work such as scientific and/or medical publications, product and commercial development and regulatory submissions by Perspectum Diagnostics. Your personal information will be de-identified before it is used for these purposes.

If other companies, for example pharmaceutical companies, contact Perspectum Diagnostics in need of participants for their own studies, Perspectum Diagnostics will **not** provide identifiable information to the third party. Participants will first be approached by Perspectum Diagnostics and if they show interest in participating in these studies, they will be given information on how to contact these companies. Perspectum may be paid for such an introduction of participants to these companies. There are no plans to pay you if that happens.

We may also contact you with information in the form of our regular newsletters, which you may unsubscribe from at any time by clicking a link in the newsletter or contacting us.

Will I get the results of this registry?

Although the LiverMultiScan is part of the registry, you may be able to view and discuss your LiverMultiScan results with a healthcare provider of your choosing. By signing this consent and giving us your healthcare provider’s contact information, you are authorizing us to send them a copy of your LiverMultiScan report.

What are the risks and possible discomforts from being in this registry?

MRI

Magnetic resonance imaging (MRI) does NOT use radiation. MRI scans are very safe and there are no known major side effects from the types of scanner that we use. The MRI scan is noisy, and we provide earplugs/headphones to protect your ears. The scan also involves lying flat in a slightly confined space and a small number of people find this too claustrophobic. It is not clear whether

magnetic resonance could potentially affect an unborn child; therefore, you should not take part in this registry if you are pregnant or think you might be.

Will I be paid to take part in this registry?

The LiverMultiScan will be provided free of cost. There are no plans to provide you with any stipend.

What will I have to pay for if I take part in this registry?

There will be no costs to you for taking part in this registry. The LiverMultiScan will be performed at no charge to you or your insurance. However, you or your insurance will be responsible for paying for a liver biopsy and other tests and blood work that your doctor may have recommended as part of your standard clinical care. In this registry, Perspectum Diagnostics is responsible only for your participation in the LiverMultiScan. Perspectum Diagnostics will pay for any injury that is not covered by your health insurer only if the injury is a direct result of your participation in the LiverMultiScan.

In the unlikely event that you are injured or get sick during the LiverMultiScan, call the principal investigator immediately. You can contact the principal investigator using the following details:

Name	Carlos Duncker
Contact Details	email: carlos.duncker@perspectum.com cell: 210-251-0040

Emergency medical treatment will be provided to you as needed. Your insurance may be billed for this treatment. The sponsor will pay any charges that are not covered by insurance policy or the government, provided the injury was not due to your underlying illness or condition and was not caused by you or some other third party. No other payment is routinely available from the investigator or the sponsor.

What happens to the information collected for this registry?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Except for the report that will be sent to your healthcare provider, your identity will not be disclosed in any other publications. Your information will be retained in accordance with local data protection laws and you may choose to withdraw from the registry at any time by contacting us.

Your private information will be shared with individuals and organizations that conduct or watch over this registry, including:

- The registry sponsor;
- People who work with the registry sponsor;
- Government agencies including the Food and Drug Administration (FDA), as applicable;
- The Institutional Review Board (IRB) that reviewed this registry

A description of this registry will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. You can search this website at any time.

Statement of Informed Consent

Signature of Subject:

Statement of Subject Giving Informed Consent and Authorization

- I have read this consent form.
- This registry has been explained to me, including risks and possible benefits (if any).
- I understand the information given to me.
- I have had the opportunity to ask questions.
- I agree to allow my health information to be used and shared as described above.
- I understand that my signature documents my consent to take part in this registry.
- I authorize Perspectum Diagnostics to contact me in the future as stated above at either my personal phone number and/or email address provided below:

Subject's Email: _____ Subject's Phone: _____

- I authorize Perspectum Diagnostics to contact my healthcare provider as stated above to provide them with a copy of my LiverMultiScan report:

Subject's healthcare provider's name: _____

Subject's healthcare provider's address: _____

Subject's healthcare provider's phone number: _____

Printed Name of Registry Subject Signature of Registry Subject Date [DD MON YYYY]

Signature of Principal Investigator or Person Obtaining Informed Consent:

Statement of Principal Investigator or Person Obtaining Consent

- I have explained the registry to the registry subject.
- I have answered all questions about this registry to the best of my ability.

Printed Name of Person Obtaining Signature of Person Obtaining Date [DD MON YYYY]