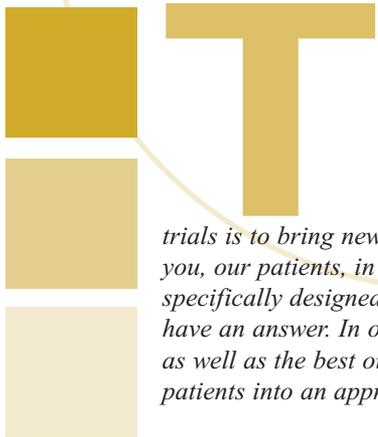


# All You Need to Know about Clinical Research



*Tulane Abdominal Transplant is committed to the advancement of basic science in both liver disease and multi-organ transplantation. By participating in clinical trials, our staff, of dedicated physicians and research coordinators, is able to efficiently study and apply the developments in basic research to our ever-growing cohort of patients. The purpose of research trials is to bring newer and hopefully better medications and therapies to you, our patients, in accordance with FDA requirements. These trials are specifically designed to answer questions for which we do not currently have an answer. In order to assure the continued advancements of the field, as well as the best outcome for patients, it is our goal to enroll each of our patients into an appropriate clinical study.*

*We carefully select research trials that we believe will offer our patients better care. Our research team meets regularly to evaluate research protocols from various industry-sponsored sources as well as our own investigators. As a group, we weigh the risks and benefits of each trial and select only those that offer the potential for the most direct benefit to our patients. We follow strict ethical requirements ensuring that these clinical trials are scientifically valid and valuable to our patient population. All trials are submitted to the Tulane Institutional Review Board (IRB) for approval and to maintain compliance with all ethical requirements.*

*Patients are fully informed prior to participation to ensure that you control whether or not you want to participate and that the research is consistent with your values and preferences. All patients are treated with equal respect regardless of whether you decide to participate. Patient privacy is managed in accordance with patient confidentiality rules and your welfare is carefully monitored throughout participation. Patient care is of utmost importance – you have the right to withdraw your participation from clinical trials at anytime without penalty and should any new information be learned which may affect your willingness to participate, you will be notified immediately.*

*Below are some frequently asked questions which have been published by clinical research professionals that will inform you of the purpose of clinical research and the benefits and risks to participating in a clinical trial:*



## Who can participate in clinical trials?

A. All clinical trials have guidelines about who can participate. Using inclusion and exclusion criteria is an important principle of medical research that helps to produce reliable results. The factors that allow someone to participate in a clinical trial are called “inclusion criteria” and those that disallow someone from participating are called “exclusion criteria”. These criteria are based on factors such as age, the type and stage of a disease, previous treatment history, and other medical conditions. Before joining a clinical trial, a participant must qualify for the study. It is important to note that inclusion and exclusion criteria are not used to reject people personally. Instead, the criteria are used to identify appropriate participants and keep them safe. The criteria help ensure that researchers will be able to answer the questions they plan to study.



## What happens during a clinical trial?

A. The clinical trial team includes doctors, research coordinators, and nurses as well as social workers and other health care professionals. They check the health of the participant at the beginning of the trial, give specific instructions for participating in the trial, monitor the participant carefully during the trial, and stay in touch after the trial is completed.

Some clinical trials involve more tests and doctor visits than the participant would normally have for an illness or condition. For all types of trials, the participant works with a research team. Clinical trial participation is most successful when the protocol is carefully followed and there is frequent contact with the research staff.



## What is informed consent?

A. Informed consent is the process of learning the key facts about a clinical trial before deciding whether or not to participate. It is also a continuing process throughout the study to provide information for participants. To help someone decide whether or not to participate, the doctors or research coordinators involved in the trial explain the details of the study. Then the research team provides an informed consent document that includes details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document. The participant then decides whether or not to sign the document. Informed consent is not a contract, and the participant may withdraw from the trial at any time.



## What should people consider before participating in a trial?

A. People should know as much as possible about the clinical trial and feel comfortable asking the members of the healthcare team questions about it, the care expected while in a trial, and the cost of the trial. The following questions might be helpful for the participant to discuss with the healthcare team. Some of the answers to these questions are found in the informed consent document.

- What is the purpose of the study?
- Who is going to be in the study?
- Why do researchers believe the new treatment being tested may be effective? Has it been tested before?
- What kinds of tests and treatments are involved?
- How do the possible risks, side effects, and benefits in the study compare with the current treatment?
- How might this trial affect my daily life?
- How long will the trial last?
- Will hospitalization be required?
- Who will pay for the treatment?
- Will I be reimbursed for other expenses?
- What type of long-term follow up care is part of this study?
- How will I know that the treatment is working? Will results of the trial be provided to me?
- Who will be in charge of my care?



## What are the side effects and adverse reactions?

A. Side effects are any undesired actions or effects of drug or treatment. Negative or adverse effects may include headache, nausea, increased risk of infection, or other physical problems. Experimental treatments must be evaluated for both immediate and long-term side effects.



## What are the benefits and risks of participating in a clinical trial?

A. Clinical trials that are well designed and well executed are the best treatment approach for eligible participants to:

### Benefits

- Play an active role in their own healthcare
- Gain access to new research treatments before they are widely available
- Obtain expert medical care at leading healthcare facilities
- Help others by contributing to medical research

## Risks

There are risks to participating in a clinical trial.

- There may be unpleasant or serious side effects
- The treatment may not be effective for the participant
- The protocol may require more of their time and attention than would a non-protocol treatment, including trips to the study site, more treatments, hospital stays or complex dosage requirements.



## How is the safety of the participant protected?

A. The ethical and legal codes that govern medical practice also apply to clinical trials. In addition, most clinical research is federally regulated with built in safeguards to protect the participants. The trial follows a carefully controlled protocol, a study plan which details what researchers will do in the study. As a clinical trial progresses, researchers report the results of the trial at scientific meetings, to medical journals, and to various government agencies. Individual participants' names will remain secret and will not be mentioned in these reports

Every clinical trial in the U.S. must be approved and monitored by an Institutional Review Board (IRB) to make sure the risks are as low as possible and are worth any potential benefits. An IRB is an independent committee of physicians, statisticians, community advocates, and others that ensures that a clinical trial is ethical and the rights of study participants are protected. All institutions that conduct or support biomedical research involving people must, by federal regulation, have an IRB that initially approves and periodically reviews the research.



## Can a participant leave a clinical trial after it has begun?

A. Yes. A participant can leave a clinical trial, at any time. If you leave a clinical trial you will be returned to standard medical treatment and will receive the appropriate medical care. When withdrawing from the trial, the participant should let the research team know about it, and the reasons for leaving the study.

Source: [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and [www.novartisclinicaltrials.com](http://www.novartisclinicaltrials.com)

*For more information about our research program or current on-going trials, please visit the Tulane Abdominal Transplant website at [www.tulanetransplant.com](http://www.tulanetransplant.com) or contact one of the clinical research coordinators at 1-888-988-5344.*