

Aspire Independent Review Board

Hello Current or Potential Research Participant:

Thank you for your interest in Aspire Independent Review Board (IRB) and the clinical research studies that we oversee. Aspire IRB has been inspected by the FDA and has been formally designated to review, approve, and monitor research involving human participants with the aim to protect their rights and welfare. An IRB reviews research to make sure that it is well-designed and that the risks are minimized. The *FDA* (<http://www.fda.gov/>) and *HHS* (<http://www.hhs.gov/>) regulations have empowered IRBs to approve, require modifications in (to secure approval), or disapprove research. Our Board is made up of physicians, scientists, non-scientists and community members, as well as some members who are affiliated with Aspire IRB. **However, it is important to understand that, even though the IRB approves the research and the facility at which it is being conducted, this does not mean that a research project is safe or that it is right for you.**

The second most important part of Aspire IRB (the first being, of course, the rights and welfare of study participants) is the research that we review and approve and/or disapprove. "Research" means a systematic investigation, including development, testing and evaluation, designed to develop or contribute to generalizable knowledge (knowledge that can be applied to a broader population than just those participants in a specific research study). Aspire IRB focuses on research that involves human subjects (participants). There are many different types of clinical research studies (sometimes called "trials" or "investigations"), such as treatment studies, prevention studies, diagnostic studies, and quality of life studies. Medical research is done to learn more about a drug, a medical device, a medical procedure, or a certain medical condition or behavior. The main goal is to find better ways to treat conditions, improve health and cure diseases for others in the future. Clinical trials are a way to help people improve their health and assist medical professionals in finding treatments that will work.

The Principal Investigator is the person responsible for conducting a research study at an approved facility. The Principal Investigator is usually a physician, but can also be a chiropractor or other type of clinician. There is a research team made up of a Principal Investigator, Sub-Investigators (other clinicians helping to conduct the study under the supervision of the Principal Investigator), research coordinators, and research nurses. The research study will follow a carefully controlled protocol which sets out a plan that the Principal Investigator is responsible for following. All details of the research study are described in the protocol and it is very important the Principal Investigator and research staff follow it exactly. The only way a research study can be conducted is if the study has a sponsor to provide funding. The sponsor may be a government agency, a pharmaceutical or device company, a public institution or an individual person. No matter who the sponsor is, they pay for the research to be done.

The Consent Form

This document will explain everything a potential participant will need to know in order to make a clear, educated choice on whether the particular research study is the right study for him/her. The consent form will explain why the research needs to be done and the potential risks and benefits of participation.

Patient vs. Study Participant

As a patient, the treating doctor uses his/her clinical judgment to do what is in the patient's best interests. A patient may be started on a certain treatment, but if that does not work, then he/she is able to switch and try something different to try and obtain different results. The doctor may determine if the treatment is working by how the patient is improving. **A doctor will always do what is best for the patient in order to try and help them improve.**

As a research participant, the Principal Investigator must follow the study protocol and provide the medical care that is specified in the protocol. Certain tests and procedures, such as randomization, use of placebos and blinding, must be followed even if the Principal Investigator would not have done something like that outside of the research study.

The research being conducted relies upon the Principal Investigator following the protocol, but will NEVER compromise your safety. If this study is not working for you, there is the possibility you may be asked to stop your participation.

Rights and Responsibilities of a Research Study Participant: (http://www.aspire-irb/pdfs/rights_and_responsibilities.pdf) Important information regarding research studies.

Essential Information: (http://www.aspire-irb/pdfs/essential_information.pdf) Additional information regarding research studies.

This information is provided to you, the study participant, to help answer any questions that you may have regarding certain aspects of clinical research. However, should you have any further questions, please contact the Principal Investigator on the study in which you wish to participate.

Thank you. We wish you the best, whether you choose to participate or not.

Aspire IRB