





San Diego

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 will 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 everything, from why the research needs to be done to the potential risks and benefits of participation.

[Rights and Responsibilities of a Research Study Participant](#): Important information regarding research studies.

### **Patient vs. Study Participant**

As a patient, the treating doctor uses his/her clinical judgment to do what is in the patient's best interest. 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 to try and help them to 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.**



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[Essential Information:](#) 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 and best wishes if you do or do not choose to participate,

Aspire IRB