Concise Summary for Consent for Early Feasibility/First in Human Device Studies

**Key Information:**

1. This research study is being done to test this newly developed device, [Name of Device] in humans in a study called an Early Feasibility Study/First in Human Study. You are free to choose whether you wish to participate in this study or not. This information is being provided to you since the study device is being studied for its use in [treatment, diagnosis or prevention of CONDITION].
2. The investigators are hoping to see how this device performs in humans, and to collect information on any effects, both good and bad, that they discover while doing the research. The device has been specifically developed to [treat, diagnosis or prevention of CONDITION]. The researchers are hoping that the device will benefit you by [treating/diagnosing or preventing your CONDITION].

The study is likely to last for [duration of study] and will involve [xxx number of visits with the study team].

[provide a brief description of the study procedures]

1. Since this device is so new, not all the effects are known at this time, but you will be monitored carefully during your participation in the study to see if you have any expected or unexpected reactions. The investigators are hoping to obtain information on whether the device can be used in the future for [treatment, diagnosis or prevention of CONDITION]. Some of the expected discomforts that you may experience during this study are: [expected risks and discomforts].
2. Treatment options that currently exist for your condition are: [Provide a brief description of what is currently available to treat the condition, if there is any treatment available, and how this device differs from currently available options for treating the condition].
3. **What else should I consider before I make my decision?**

*[Briefly describe if there is any other important information a potential participant may want to know before participating in this study (i.e. potentially burdensome time commitments, cost considerations, significant QOL issues). Include “*Early withdrawal or termination from this study might mean that there is no longer any treatment/diagnostic/prevention option available for your condition” *if applicable*.*]*

**Please review the rest of this document for additional details about these topics and other information you should know before making a decision about participating in this research.**