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| *This “Patient Introduction to Consent for Early Feasibility Studies” may be provided as an educational aid to patients considering participation in Early Feasibility Studies (EFS) in the United States. An Informed Consent Form (ICF) that has been approved by the IRB is required to be signed by the patient prior to screening and enrollment in an EFS. An ICF Template specifically prepared for EFS can be found on the MDIC website (*<http://mdic.org/cts/efs/spi/>*). The information contained in this document and the ICF template are based on FDA Guidance, “Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies Guidance for Industry and Food and Drug Administration Staff,” issued on: October 1, 2013.* |

**Patient Introduction to Consent for Early Feasibility Studies**

You may meet the eligibility requirements to participate in an Early Feasibility Study (EFS) of a device to treat your current medical problem. The information below provides background information related to early feasibility studies (EFS) in the US and offers points to keep in mind when considering participation in an EFS.

**Key Points**

* EFS are often performed as a first study to find new treatments for medical conditions for which current therapies are: (1) not available, or (2) have safety or effectiveness concerns.
* Participation in an EFS means you may gain early access to a new device option for your medical problem.
* EFS are for devices that have only limited or no prior experience with use in humans with your medical problem. This means:
* We do not yet know all the potential benefits or risks associated with the device, and
* We are not sure that participating in the study will improve your health.
* Participation in an EFS may advance the care for others with your medical condition.
* An EFS requires approval by the US Food and Drug Administration (FDA), which will monitor study progress
* An EFS includes special measures to help protect your health and lower your risk of harm.

**The EFS Initiative**

The EFS Initiative is a partnership among doctors at clinical research institutions, industry, and US government regulators of medical devices. Its goal is to improve access of potentially beneficial medical devices to US patients. In the past, devices often underwent initial clinical testing in Europe before they were available for testing in the US. The EFS initiative can streamline device research in the US, therefore enabling US patients earlier access to potentially helpful medical technologies.

**What is an “Early Feasibility Study”?**

All medical devices undergo rigorous testing overseen by the FDA before human use, but their performance, safety, and benefits can only be completely assessed after use in a large number of patients. Use of a medical device is considered “early” if doctors have had limited or no prior experience using the device in humans to treat a specific medical problem. “Limited experience” means that the possible benefits and risks of using the device are not yet fully known. This also means that if you participate in a research study involving a medical device with limited experience, it is not certain whether or not the device will improve your health. EFS are generally designed to show that the device and the procedure(s) for its use are basically safe and that the device does what it is designed to do to treat your condition.

**What are the types of studies and options under EFS?**

There are several types of EFS depending on the device itself and the condition being treated. For example, an EFS may test (1) a new device to treat conditions for which no safe or effective therapy currently exists; (2) a new device with potential advantages compared to available therapies; (3) a new device for a condition in which there are currently available safe and effective treatments; (4) the next generation of a currently approved device (a newer model) that may perform better than the older version; and (5) an approved device to treat a medical condition that is different from its current approved use.

The study you may be eligible for is: *[insert type of study and potential risk]*

**What does participation in an EFS mean for me?**

If you choose to participate in an EFS, you would be among the first patients in the US, and possibly the world, to receive the device. Participation in an EFS means that you will gain early access to a device that may improve your health or advance medical care for other patients like you. However, it is also possible that you may experience side effects or complications that we cannot anticipate at this point in time. More information on the potential benefits and risks associated with your participation in the EFS is provided in the informed consent, a detailed document you will be required to read and sign prior to enrolling in the EFS. The informed consent process gives you a chance to think about the study in more depth and ask your doctor or the study team any questions that you may have.

**What safeguards are in place for my protection as an EFS participant?**

Consideration of the safety and well-being of patients is of the highest importance, and special measures are included in the design and conduct of an EFS to help protect your health and lower the risk of harm; however, because of the early stage in evaluation of EFS devices, your safety cannot be guaranteed. Further, you do have rights, including the right not to participate in the EFS, and the right to stop participating in a study at any time. Steps have also been taken to protect your privacy and confidentiality if you participate in an EFS.

Multiple steps to minimize risks for EFS participants have been incorporated in the study. These include:

* Careful selection of patients for the study;
* Close monitoring to allow for timely stopping the study if needed;
* Study oversight by the FDA with pre-set time frames for data review from enrolled patients; and
* Study oversight by an Institutional Review Board (IRB).  An IRB is a group authorized by Federal Regulations to protect patient rights and welfare when a patient decides to participate in clinical research as study subject.

**Who should I contact if I have questions?**

You should always discuss any questions with your doctor or the research study team.