Background Information on Early Feasibility Studies

This background information on Early Feasibility Studies (EFS) is intended to provide hospital administration, Institutional Review Boards (IRBs), Ethics Committees, Research Staff at clinical sites/institutions and others involved in the execution of EFS information on key elements for conduction 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.

The information below provides background information on early feasibility studies (EFS) in the US and offers points for patients to consider when contemplating enrolling patients.

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 patients may gain early access to a new device option for their medical problem.
- EFS are conducted for devices that have only limited or no prior experience with use in humans for the proposed indication for use. 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 a patient’s health condition.
- Participation in an EFS may advance the care for others with the same medical condition being treated in the study.
- 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 patient health and lower their risk of harm.

The EFS Initiative

The EFS Initiative is a partnership among doctors at clinical research institutions, industry, US government regulators of medical devices, and the Medical Device Innovation Consortium (MDIC). 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 a patient participates in a research involving a medical device with limited experience, it is not certain whether or not the device will improve their 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 and can be use as intended.
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.

What does participation in an EFS mean for the patient?
If a patient chooses to participate in an EFS, they would be among the first patients in the US, and possibly the world, to receive the device. Participation in an EFS means that the patient will gain early access to a device that may improve their health or advance medical care for other patients with the same medical condition. However, it is also possible that they 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 participation in the EFS is provided to the patient in the informed consent, a detailed document which patients are required to read, and sign prior to enrolling in the EFS. The informed consent process gives patients a chance to think about the study in more depth and ask their doctor or the study team any questions that they may have.

What safeguards are in place for patient 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 study participant health and lower the risk of harm. However, because of the early stage in evaluation of EFS devices, safety cannot be guaranteed. Further, patients do have rights, including the right not to participate in the EFS, and the right to stop participating in the study at any time. Steps have also been taken to protect the safety, welfare, and privacy of EFS subjects.

Multiple steps to minimize risks for participants have been incorporated in the EFS investigational plan, these include:

- Careful selection of patients for the study;
- Close monitoring to allow for timely stopping the study if needed; and
- Study oversight by the FDA with pre-set time frames for data review from enrolled patients

Who will patients be advised to contact if they have questions?
Patients will be advised to always discuss any questions with their doctor or the research study team.