**Consent Form Module: Device Study Descriptions**

**Version 2, June 12, 2015**

***For device studies, describe the FDA status of the device in a way the subject is likely to understand, so that the subject knows the FDA’s ruling on the safety and effectiveness of the device and the FDA indication(s) for the device, for example:***

***For market-approved or cleared (e.g., 510(k)) devices when the device will be used ON indication:***

The medical device that we are studying, \_\_\_ [name device], has been approved by the U.S. Food and Drug Administration for patients with \_\_\_\_\_[condition]. We want to collect more information about the safety/effectiveness of the device / - OR - / we want to compare how patients treated with this device do when compared to \_\_\_\_\_.

***For market-approved or cleared (e.g., 510(k)) devices when the device will be used OFF indication:***

While the medical device that we are studying, \_\_\_\_ [name device], has been approved by the U.S. Food and Drug Administration for patients with \_\_\_\_\_\_ [approved indication], we will be using the same device for a different purpose. For this reason this use must be considered experimental. We want to collect information about the safety/effectiveness of the device when used in this way / - OR - / we want to compare how patients treated with this device do when compared to \_\_\_\_\_\_\_.

***For devices the FDA considers Investigational Device Exemptions (IDEs), OR when the device is considered to be Non-Significant Risk (NSR)*:**

The U.S. Food and Drug Administration considers the device we are studying, \_\_\_\_\_ [name device], to be experimental while researchers study how safe it is and how well it works. We do not know all the ways that \_\_\_\_\_ [device] may affect people.

***For Humanitarian Use Devices (HUDs) with Humanitarian Device Exemption (HDE) status, when the device will be used ON-indication*:**

The U.S. Food and Drug Administration has given the device we are studying, \_\_\_\_\_\_ [name device], a special status because while there is some information that the device is safe and possibly effective, there are simply not enough patients with \_\_\_\_\_\_ [indicated condition] to test its safety and effectiveness in the usual ways.