Appendix 5.3.3
Circumstances Under Which Investigational Devices Can Be Used Outside an IDE-Approved Clinical Trial[1]

Type of Access	Description	Timing
Emergency Use	May occur before an IDE is approved if the disease or condition is deemed life-threatening, no alternative exists, and there is no time to obtain FDA approval. In these instances, the IRB and a physician not participating in the investigation must review and approve the investigation. The sponsor of the use must also submit a separate IDE application to FDA.	Before or after initiation of trial
Compassionate Use	Refers to the treatment of seriously ill patients using an unapproved device when no other available treatments have been deemed satisfactory *and* the patient does not qualify for the conventional clinical trials being conducted due to unrelated health problems, age, or other factors. Prior FDA approval is needed before compassionate use occurs, and in no case should a physician treat a patient with the device before then. FDA approval for compassionate use is granted via the submission of an IDE supplement, in which the physician requests approval for a protocol deviation. When making a determination about compassionate use, the FDA considers whether the preliminary evidence of safety and effectiveness justifies such use and if it would interfere with the conduct of a clinical trial to support marketing approval.	During clinical trial
Treatment Use	Facilitates the availability of promising new devices to larger groups of seriously ill patients as early as possible by making promising new technologies available before the completion of all clinical trials. The FDA approves such usage under a treatment IDE application. Treatment use may begin 30 days after FDA receives the treatment IDE submission, unless the FDA responds to deny treatment use or to require modifications to the proposal made in the application.	During clinical trial
Continued Access	Refers to the continued enrollment of subjects after the controlled clinical trial under an IDE has been completed. This is typically done to provide patients with access to the investigational device while the marketing application is being prepared by the sponsor and/or reviewed by the FDA. Continued access is generally granted if there is a public health need or preliminary evidence demonstrates	After clinical trial

Type of Access	Description	Timing
	that the device is effective and there are no significant safety concerns.	

[1] "IDE Expanded/Early Access," U.S. Food and Drug Administration, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm (March 30, 2014).

