

## **FDA approval and IRB chair concurrence are required before the use of the device.**

### **Submit iStar application for Chair Concurrence**

1. Log on to the iStar IRB system.
2. Click on “Create New Emergency Use/Expanded Access Application”
3. Complete all fields.
4. In Section 1.6 choose “Expanded Access (Compassionate Use)”
5. In Section 1.7 indicate whether an uninvolved physician written statement of concurrence was obtained. If there was not sufficient time to obtain an uninvolved physician’s assessment, explain why at Section 1.7.1.
6. In Section 1.8 choose “Yes” to indicate that the emergency use of the device has already taken place.
7. In Section 1.10 upload the following documents:
  - FDA Authorization letter/correspondence to proceed with single patient treatment
  - The informed consent that will be given to the patient. (See the IRB template for Expanded Access)
  - The treatment protocol or treatment plan
  - The device Instructions for Use or product information (or other source that describes the risks and potential benefits of the investigational device)
  - Uninvolved physician’s written statement of concurrence
8. Click “Continue” then “Submit Application”