

The investigational medical device has already been used. (Submit to IRB within 5 days of use)

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 “Emergency Use”
5. In Section 1.6.1 indicate the regulatory status of the device and provide the additional information where prompted
6. 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.
7. In Section 1.8 choose “Yes” to indicate that the emergency use of the device has already taken place.
8. In Section 1.9 check all boxes to provide assurances that the criteria for emergency use have been met.
9. Complete Section 3 of the application.
10. In Section 3.4 upload
 - an unsigned version of the consent document that was used
 - the written statement of concurrence from an uninvolved physician
 - documents provided by the sponsor (investigators brochure, treatment plan, etc.)
11. If informed consent and/or an uninvolved physician’s concurrence was not/could not be obtained, indicate the reason in Section 3.5.1 and 3.5.2.1.
12. Click “Continue” and then “Report Usage to IRB.”