

The investigational drug/biologic *has already been administered.*

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 1.8 choose “Yes”
6. In Section 1.9 check all boxes to provide assurances that the criteria for emergency use have been met.
7. Complete Section 3 of the application.
8. In Section 3.4 upload
 - the Emergency IND approval from the FDA
 - an unsigned version of the consent document that was used
 - the written statement of concurrence from an uninvolved physician
 - FDA Form 3926 (check box 10b)
 - documents provided by the sponsor (investigators brochure, treatment plan, etc.)
9. 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.
10. Click “Continue” and then “Submit Application.”