

The physician has requested to use alternative IRB review procedures from FDA

Submit iStar application for Chair Concurrence

1. Log on to the iStar IRB system.
2. From the Dashboard, click on “Create New Emergency Use/Expanded Access Application”
3. Complete all sections of the iStar application.
4. In Section 1.6 choose “Expanded Access [Compassionate Use].”
5. In Section 1.6.5 indicate that you have requested authorization from FDA to use alternative IRB review procedures. ***This request is made by checking box 10b of FDA Form 3926. If box 10b is not checked (or a separate waiver from FDA was not requested), the iStar application must be withdrawn and a new full application submitted for full committee review.***
6. In Section 1.10 upload the following documents:
 - Completed [FDA Form 3926](#) with box 10b checked
 - 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, if a treatment plan was not outlined in FDA Form 3926
 - The investigators brochure or product information (or other source that describes the risks and potential benefits of the investigational treatment)
7. Click “Continue” and then “Submit Application.”

NOTE: Treatment may not begin until you have received correspondence from the IRB that indicates IRB approval or Chair Concurrence