No request to or approval from FDA for alternative IRB review procedures

Submit iStar application for Full Committee review

1. Log on to the iStar IRB system.
2. From the Dashboard, click "Create New Study"
3. Complete all sections of the iStar application.
4. In Section 1.1 choose "Research Protocol or Study on Human Subjects"
5. In Section 5.2 upload the treatment plan/protocol.
6. In Section 17 include the applicable IND information, IND acknowledgement letter, and the product information (investigators brochure)
7. In Section 24 upload the informed consent document that will be given to the patient.
8. Submit the iStar Application
9. The application will be reviewed by the convened committee.

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