Emergency Use of an Investigational/Unapproved Drug or Biologic for a Single Patient

2024

The investigational drug/biologic *will be administered in the next 5 days* (2 step submission).

STEP 1

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 "No"
6. In Section 1.9 check all boxes to provide assurances that the criteria for emergency use have been met.
7. Click "Continue" and then "Submit Application."

STEP 2 – AFTER DRUG/BIOLOGIC IS ADMINISTERED

1. In current application, click "Edit Emergency Use Application"
2. In Section 1.8, change the answer to "Yes"
3. Click "Continue" to Section 3 of the application.
4. Complete Section 3 of the application.
5. 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.)

6. 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.

7. Click "Continue" and then click "Report Usage to IRB" and "Finish"