

Note (0 Notes Total) Add Delete

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## 01-4. Emergency Use Device

Completion of this section is required based on the response provided to question 1-1.1.

1-4.1\* Provide the single-patient IDE number:

The HDE holder should contact the FDA to obtain this number

1-4.2\* Describe the patient's condition and the circumstances necessitating treatment, including the justification for not enrolling the subject in an established study.

1-4.3\* Discuss why alternative therapies are unsatisfactory and why the probable risk of using the investigational device is no greater than the probable risk from the disease or condition.

1-4.4\* Describe any deviations from the approved clinical protocol that may be needed in order to treat the patient. Provide IRB tracking number if the clinical protocol was approved by a UM IRB. Clinical protocols approved by a non-UM IRB must be uploaded below.

Provide the HUM # for the HUD application.

Upload non-UM IRB approved clinical protocol here.

Add

Name	Version
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There are no items to display

1-4.5\* Was or will consent be obtained before administration of the device?

Select one:

Yes

No

Clear

1-4.5.1\* What type of informed consent process was or will be implemented prior to administration or application of the test article to the patient?

Select one:

IRBMED emergency use template

Sponsor-provided informed consent document

Other informed consent document

Clear

Upload a copy of the unsigned (to protect patient privacy) informed consent document here:

	Name	Version
<input type="checkbox"/>	[Edit] icd	0.03

**1-4.6\*** Provide the start and end dates of administration or application of the investigational device to the patient.

**1-4.7\*** If the device has been administered, provide any information on the patient's response.

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