

DECATUR MEMORIAL HOSPITAL
INSTITUTIONAL REVIEW BOARD

APPLICATION FOR CONCURRENCE OF EMERGENCY USE OF UNAPPROVED MEDICAL
DEVICE

Date:

Physician:

Name of Device:

Sponsor:

Patient:

Date of anticipated device use:

All of the following conditions must exist to justify emergency use:

1. The patient has a life threatening* condition that needs immediate treatment.
 Yes No
2. There is no generally acceptable alternative available for treating the patient.
 Yes No
3. Because of the immediate need to use the device, there is no time to use existing procedures to obtain FDA approval for the use.
 Yes No

**Life threatening:* means a stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.

Please provide the following details of this emergency use case (attach additional pages if needed):

- Describe the patient's life-threatening condition that needs immediate treatment:

- Provide your professional opinion as to why there is no generally acceptable alternative available for treating the patient.

- Confirm that because of the immediate need to use the device, there is not time to use existing procedures to get FDA approval for the use:

Attach:

- Independent assessment by an uninvolved physician.
- Informed consent (or appropriate documentation of exception)

This application has been reviewed an approved by:

Dr. Michael Zia, Vice President, DMH

Date

DMH Department Chairperson

Date

This application has been reviewed and meets the requirements of 21 CFR 56.102(d) for emergency use of an unapproved device.

DMH IRB Chairperson

Date