

It is recognized that sufficient time may not exist to obtain IRB concurrence prior to the use of the device. In that case, IRB concurrence will be deferred. *The physician is still required to obtain institutional approval via the Vice President of Quality Systems and the Chairperson of the applicable department prior to use of the device and to file a report with the IRB within 5 working days of use of the device.*

Informed Consent:

The physician is required to obtain informed consent of the patient prior to the emergency use; this consent should contain all of the elements of consent that are required in the usual DMH Investigational Consent process. However, an exception to this rule may be made if, as stated in 21 CFR §50.23(a):

“...(B)oth the investigator *and* a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:

1. the human subject is confronted by a life-threatening situation necessitating the use of the test article;
2. informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from the subject;
3. time is not sufficient to obtain consent from the subject’s legal representative;
4. no alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject’s life.”

If, in the physician’s opinion, immediate use of the test article is required to preserve the subject’s life, and if time is not sufficient to obtain an independent physician’s determination that the four conditions above apply, the physician should make the determination and, within 5 working days after the use of the device, have the determination reviewed and evaluated in writing by a physician who is not participating in the clinical investigation of the device. Written documentation of the evaluation must be provided to the IRB with the physician’s report that is due 5 working days after the use of the device.

After-Use Procedures:

The physician is required to submit a report to the IRB within 5 working days of use of the device. (See “Emergency Use of Unapproved Medical Device: Physician Report”)

The report will be presented at the next scheduled meeting for review and ratification.

Considerations for Future Requests:

Subsequent use of the device may *not* occur unless the physician obtains approval of an IDE for the device and its use and the study undergoes prospective, full IRB review and approval. This is true regardless of whether the same physician or a different physician wants to administer the investigational device. If an IDE application for subsequent use has been file with the FDA and the FDA disapproves the IDE application, the device may not be used even if the circumstances constituting an emergency exist.

Data:

Emergency use is deemed clinical use of an unapproved device. It is not research. Information about the patient’s response may not be included with research data or reported in any publication.

VOTING REQUIREMENTS:

Except when review by the Chairperson is used, review of emergency use will be accomplished at a convened meeting at which a majority of the IRB members are present, including at least one member whose primary concerns are in nonscientific areas. Concurrence requires the ratification of a majority of those members present at the meeting. No member with a conflict of interest shall deliberate or vote on the emergency use in which a conflict exists. The physician requesting the concurrence will not be present for deliberation or voting.

DOCUMENTATION:

- 1) Request for Concurrence filed prior to use of the investigational device: Every effort will be made to inform the physician in writing within 24-48 hours or less of the determinations made by the IRB Chairperson, DMH Vice President of Quality Systems and the Chairperson of the applicable Department. Notification will be via appropriate signatures on the Application for Concurrence of Emergency Use of an Unapproved Medical Device Form.
- 2) Emergency Use of Unapproved Medical Device: Physician Report. The physician will be informed in writing, within ten days following the meeting date, of the decision made by the IRB. The IRB secretary via letter will notify the physician of the action taken
- 3) It is the physician's responsibility to inform the study sponsor and the FDA of the results of the IRB review.
- 4) Written documentation of IRB actions will be sent to DMH Administration within ten days following the meeting date of the IRB decision. IRB meeting minutes shall be made available for Administrative review upon request.
- 5) The IRB minutes shall document meeting attendance, actions taken by the IRB, the vote on those actions, including the number of members voting for, against, and abstaining, the basis for requiring changes in or disapproving the research, a written summary of the discussion of controverted issues and their resolution, and a statement regarding compliance with prohibition of deliberation and voting by Investigators/IRB members with a conflict of interest (if applicable). The name of the abstaining member(s) will be included in the minutes. If a telephone conference call is utilized, the minutes will clearly document that the requirements have been satisfied (See "IRB Voting Requirements Policy).

APPLICABLE TO: Physicians/Investigators, Institutional Official (Vice President, Quality Systems), Chairperson of the applicable Department, IRB members

APPROVED BY:

President and CEO