

HUMAN INVESTIGATION COMMITTEE

NOTIFICATION OF EMERGENCY USE REPORT

Notice to the Committee of an emergency use of an investigational drug, biologic or device for a life-threatening condition for which no standard acceptable treatment was available and in which there was not sufficient time to obtain IRB approval.

Patient's Initials

Name of drug/biologic/device

IND or IDE#

Sponsor

- I. Briefly summarize the patient's condition, indicating in what way it was life-threatening. Briefly describe the product, and how it was used.

- II. Briefly discuss the basis for your determination that there were not any alternative approved drugs, devices or generally recognized therapies that would have provided an equal or greater likelihood of saving the patient's life (for example, what would have been done if the investigational product were not available)? If so, why were these alternatives not satisfactory?

- III. Was it urgent that treatment begin before a protocol could be reviewed by the IRB? What would have been the likely consequences of such a delay?

- IV. Document and explain any exception from the informed consent requirements.

Signature and name of physician

Date

Please Note: Any data from this Emergency Use may not be used for research purposes. The patient identified above is not a human subject of research and may not be counted as one for research purposes. If you anticipate the need to use the investigational drug, device or biologic in additional patients, prior review and approval by the Committee will be required.

Form Approved/Revised: 8/00
(Date)