If a letter is requested, the IRB office can generate a letter to be signed by the IRB chair acknowledging notification of emergency use of the test article.

The IRB letter should indicate only knowledge of, acknowledgment of, or appropriate notification of the use of the test article. The IRB letter should not indicate IRB review or approval.

(Example of letter to IRB)
Date

Dear Dr. (IRB Chair name),

Please regard this notice as a request for an IRB Emergency-Use Exemption for the use of the ***drug xxx*** for one patient (***initials***).

According to FDA regulations, in order to qualify for an emergency-use exemption, the situation must involve a "life-threatening situation in which no acceptable standard treatment is available and in which there is not sufficient time to obtain full IRB approval."

This situation complies with the definition because the patient (***describe why the patient needs the drug in a timely manner***)…

Consent from the patient will be obtained…[explain the process so that the patient understands that the drug is not FDA approved for this use and if a consent form will be used state so and include with this memo].

The data for this patient will not be used as part of a prospective research protocol.

(Example of letter to Physician – from the IRB)

Provider Name
Provider address

Attention: Research coordinator, if applicable

Re: Emergency Use of a Test Article

Name of test article and initials of patient

Date:

Dear Dr. (***Name***),

On (date of notification) the Institutional Review Board was notified of the one time emergency use of (name drug/device) for one patient (patient initials). *Insert details from the report i.e. what was the patient's diagnosis/disease, reason for use of drug device. Why does the provider feel there were no other options?*

Based on the information provided we understand that:

- The patient was in a life-threatening condition that needed immediate treatment;
- There was no acceptable alternative for treating the patient available;
- There was not sufficient time to obtain IRB review and no time to use existing procedures to get FDA approval for this use

Prior IRB review and approval are not required for the emergency use of a test article as described in 21 CFR 56.102(d) and 21 CFR 56.104(c). This letter is not a notification of IRB review or approval.

The notification you provided to the IRB meets the our requirements and federal regulations.

Please make sure that your notes document the steps that you took to ensure appropriate reporting to the IRB and sponsor (such as a copy of the report of emergency use of a test article).

Any documentation you receive from the sponsor or the FDA in regards to this emergency use should be copied to the Office of Research Compliance at MMC.

The IRB will be made aware of this Emergency Use at the next scheduled IRB meeting on XX/XX/XXXX.

Please feel free to call our office if you have any questions (Research Compliance Office, 207-396-8183).

_____
Eric Larsen, M.D., IRB Chairman