Physician's Checklist for an IND Application for Emergency Treatment

Emergency IND Sponsor's name and contact: _____

After the telephone call to FDA, record information here

IND Application # assigned _____ Date: _____

FDA Contact Name /Division/Phone _____

There is no required format for submitting this information. This format is voluntary for convenience in faxing or emailing the information that helps determine the regulatory action on this request. If the request is approved, an IND application number will be issued by the FDA, and the treating physician (or the IND application's sponsor) will be notified. Once the emergency IND application is in effect, the manufacturer may ship the drug directly to the treating physician.

1. SPONSOR INFORMATION If there is no other IND sponsor, references to the *sponsor* will mean the treating physician.

TREATING PHYSICIAN:

Name:_____ Fax: _____

Affiliation:_____ Address:_____

Phone:_____ Email:_____

SPONSOR OF THE EMERGENCY IND APPLICATION: Name and address (if different from above): _____

2. CRITERIA FOR EMERGENCY INVESTIGATIONAL NEW DRUG (IND) APPLICATION

All of the following must apply to this Emergency IND application

☐ The patient cannot emergently obtain appropriate treatment via alternative means (e.g., an approved drug, or an ongoing clinical trial, or another expanded access program)

☐ There is no comparable or satisfactory alternative therapy to treat the patient's life-threatening or severely debilitating disease or condition, and

☐ The potential benefits to the patient justify the potential risks of the treatment and the risks from this investigational treatment are not unreasonable in the context of the disease or condition treated with this investigational product

NOTE: The requested emergency use of this investigational product must not interfere with the initiation, conduct or completion of clinical investigations that could support marketing approval of the expanded access use and must not otherwise compromise the potential development of the expanded access use

3. DRUG SUPPLY REFERENCE STATEMENT AND INVESTIGATIONAL NEW DRUG PRODUCT INFORMATION

☐ IND supplier (e.g., product's manufacturer) has been contacted

☐ The IND supplier has agreed to provide the investigational drug and the right of reference to supporting information from their existing IND application or Drug Master File (DMF)

The existing IND application # (if applicable) DMF # (if applicable)

INVESTIGATIONAL NEW DRUG PRODUCT INFORMATION:

☐ Manufacturer _____

☐ Product's Name _____

☐ Dosage Form _____

☐ Route of Administration _____

☐ Dosing Regimen _____ (Include loading and maintenance doses, if applicable) _____

4. INVESTIGATOR'S QUALIFICATIONS STATEMENT
Specify the training, experience, and licensure of the treating physician

Briefly specify qualifications to administer the IND treatment (or attach CV):

CV attached: Yes ☐ No ☐

NOTE: The investigational drug treatment cannot be initiated until FDA's authorization has been received

5. PATIENT'S INFORMATION

Patient's ID (*Initials/Code #, if applicable*) _____

Gender ☐ male ☐ female

DOB _____ mo _____ day _____ year

Weight _____

Race _____

Diagnosis _____

Disease status _____

Other therapies previously administered to the patient for this condition and the response to previous therapies:

_____

Facility for treatment administration _____

☐ Additional information to support the diagnosis is attached (e.g., may attach a brief history and physical findings, diagnostic laboratory results, etc.)

6. PROPOSED TREATMENT PLAN
A relevant reference to a published treatment protocol or journal article is appropriate, if available.

Rationale for the proposed treatment: _____

Patient monitoring procedures: _____

Modifications for toxicity (e.g., dose reduction or treatment interruption): _____

7. INFORMED CONSENT AND INSTITUTIONAL REVIEW BOARD (IRB) NOTIFICATION

☐ Obtain Informed Consent from the patient or their representative prior to initiating the investigational treatment

NOTE: Notify the Institution's IRB of this emergency treatment within 5 days

Emergency IND application sponsor's name_____Date_____Signature_____

8. FOR FDA USE ONLY

IND application #:_____FDA Official's Name:_____ Date:_____

To call FDA:
During Business Hours (Mon - Fri: 8:30 a.m. to 5 p.m. E.T.): Division of Drug Information (888)463-6332 or (301)796-3400 or the appropriate Review Division in the Office of New Drugs in CDER
After Hours: FDA Office of Crisis Management & Emergency Operations Center (866) 300-4374 or (301)796-8240