

[Date]

[Regulatory Authority Name, e.g., FDA/EMA]

[Department Name]

[Address]

**RE: Request for Patient-Specific Compassionate Use (Expanded Access) Treatment**

Dear [Name of Contact Person or Reviewing Committee],

I am writing to formally request authorization for the compassionate use of [Investigational Drug/Device Name] for my patient, [Patient Name], who is suffering from [Name of Serious or Life-Threatening Condition].

**Patient Clinical Background:**

[Briefly describe the patient's medical history, current diagnosis, and the severity of their condition.]

**Rationale for Request:**

[Explain why existing approved therapies are exhausted, ineffective, or contraindicated. State why the requested investigational treatment is the only viable option and the potential clinical benefit expected.]

**Treatment Plan:**

[Detail the proposed dosage, frequency, and duration of treatment. Outline the monitoring procedures to ensure patient safety.]

**Manufacturer Approval:**

The manufacturer, [Company Name], has agreed to provide the investigational product for this specific patient use, pending your authorization. Attached is their Letter of Authorization (LOA).

**Informed Consent:**

I confirm that I have obtained written informed consent from the patient (or legal guardian), outlining the experimental nature of the treatment and the potential risks involved.

Thank you for your urgent consideration of this request. I am available to provide any additional documentation required.

Sincerely,

[Physician Signature]

[Physician Name, MD/DO]

[Medical License Number]

[Institution/Hospital Name]

[Phone Number]

[Email Address]