

[Date]

[Name of Regulatory Authority]

[Department/Division Name]

[Street Address]

[City, State, Zip Code]

RE: Request for Compassionate Use Exemption for [Patient Name]

To the Regulatory Board,

I am writing to formally request a Compassionate Use Exemption for my patient, [Patient Name], to gain access to [Name of Investigational Drug/Device/Treatment].

Patient Diagnosis:

The patient is currently suffering from [Name of Disease or Condition]. This is a [serious/life-threatening] condition for which there are currently no satisfactory alternative therapies available or authorized in this jurisdiction.

Clinical Justification:

[Patient Name] has exhausted all conventional treatment options, including [List previous treatments]. Based on current clinical data and the patient's specific medical history, I believe that [Investigational Treatment] offers a potential clinical benefit that outweighs the known and unknown risks.

Treatment Plan:

The treatment will be administered at [Institution/Hospital Name] under my direct supervision. We have obtained preliminary agreement from the manufacturer, [Manufacturer Name], to provide the product should this exemption be granted.

Monitoring and Reporting:

I commit to rigorous monitoring of the patient for any adverse effects and will provide regular progress reports to the Board as required by regulatory guidelines.

Included with this letter are the patient's medical records, a signed informed consent form, and the manufacturer's letter of intent.

Thank you for your urgent consideration of this request.

Sincerely,

[Physician Signature]

[Physician Name, MD/DO]

[Medical License Number]

[Contact Phone Number]

[Email Address]