

[Physician Name]
[Clinic/Hospital Name]
[Address]
[City, State, Zip Code]
[Phone Number]
[Email]

[Date]

[Manufacturer Name]
[Department, e.g., Expanded Access Program]
[Address]
[City, State, Zip Code]

RE: Compassionate Use Request for [Patient Name] (DOB: [Date of Birth])

To the Expanded Access Review Committee,

I am writing to formally request compassionate use access to [Investigational Drug/Product Name] for my patient, [Patient Name], under the manufacturer's expanded access protocols.

Patient Clinical Summary:

My patient is currently diagnosed with [Diagnosis/Condition]. The patient's condition is [serious/life-threatening] and has reached a stage where [describe current status].

Treatment History:

We have exhausted all FDA-approved treatment options, including [List previous treatments/medications]. These therapies have been unsuccessful due to [reason: lack of efficacy, intolerance, etc.]. Furthermore, the patient is ineligible for current clinical trials because [state reason, e.g., geographic constraints or specific exclusion criteria].

Rationale for Request:

Based on the patient's clinical profile and available data regarding [Investigational Drug Name], I believe there is a reasonable expectation that this treatment may provide a meaningful clinical benefit. The potential benefit of the treatment outweighs the known and unknown risks in this specific case.

Physician Commitment:

If this request is granted, I agree to:

- Obtain Institutional Review Board (IRB) approval.
- Comply with all FDA regulatory requirements for expanded access.
- Monitor the patient closely and report all adverse events to [Manufacturer Name].
- Maintain strict records regarding the administration and disposal of the product.

Please find the attached clinical documentation and medical records supporting this request. I look forward to your prompt review as time is of the essence for this patient's care.

Sincerely,

[Physician Signature]

[Physician Printed Name]

[Medical License Number]