[Institutional Review Board Name]
[Institution Name]
[Address]
[City, State, Zip Code]
[Phone Number]
[Email Address]

Date: [Date]

To: [Requesting Physician Name]
Department: [Department Name]
Institution: [Hospital/Clinic Name]

RE: IRB Clearance for Expanded Access / Compassionate Use

Patient Name: [Patient Name or ID Number]
Diagnosis: [Medical Condition]
Investigational Drug/Device: [Name of Product]
Manufacturer: [Company Name]
IND/IDE Number: [Number, if applicable]

Dear Dr. [Physician Last Name],

The [Institutional Review Board Name] has reviewed your request for the compassionate use of [Investigational Product Name] for the patient identified above. This request was reviewed under the [Emergency Use / Individual Patient Expanded Access] provisions of the FDA regulations (21 CFR 312 or 21 CFR 812).

Based on the clinical documentation provided, the IRB Chairperson or designated reviewer has determined that:

- The patient has a life-threatening or severely debilitating condition.
- There is no comparable or satisfactory alternative therapy available.
- The potential benefit to the patient justifies the potential risks of the treatment.

Determination: The IRB formally grants **[Approval / Concurrence]** for this single-patient compassionate use request.

Responsibilities of the Requesting Physician:

1. **Informed Consent:** You must obtain and document legally effective informed consent from the patient or their legal representative using the IRB-concurred consent form.
2. **FDA Reporting:** You are responsible for maintaining all required FDA documentation and obtaining necessary authorization from the manufacturer.
3. **Adverse Events:** Any serious or unexpected adverse events must be reported to the IRB and the manufacturer immediately.

4. **Follow-up Report:** A written summary of the treatment results and patient outcome must be submitted to the IRB within [Number] days of the conclusion of treatment.

This clearance is limited strictly to the individual patient and product specified in this application.

Sincerely,

[Signature]
[Name of IRB Chair or Administrator]
[Title]
[Institutional Review Board Name]