Context Therapeutics Expanded Access Program (EAP)

EAP Request Details – To be Completed by Requester	
Contact Information (Note "NA" for items not applicable.)	
1.	Name of physician or regulatory agency requestor:
2.	Name of institution (if applicable):
3.	Physician/institution address:
4.	Physician phone number:
5.	Physician email:
Proposal Information	
6.	Name of drug being requested:
7.	Description of patient disease or condition (do not include any patient identifiable information or personal data):

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8. Patient history (e.g. diagnosis, prior treatment history, history/results of genetic testing, current clinical status).
9. Scientific rationale for expanded access use of the drug. Include safety and efficacy data of patient's treatment history as evidence of an appropriate risk-benefit analysis and support the use of the investigational drug/biologic for the specific EAP.
10. Proposed patient treatment plan, including dose and duration:
Site Capabilities
11. List investigation drug current storage capability (e.g. controlled room temperature, secured):

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Physician Attestation

- I am a physician duly licensed and authorized to practice medicine in the jurisdiction in which I intend to administer an investigational drug (provide a copy of your CV and medical license)
- I attest that treatments to the disease have been exhausted and the patient is no longer responsive to, or able to tolerate, these therapies and there are currently no other viable therapy options, including participation in ongoing relevant clinical trials
- I will use the investigational drug only for the patient for whom the supply of investigational drug is being requested.
- I acknowledge that this investigational drug will be supplied under my direct personal responsibility and I am responsible for all communications with the patient
- I will obtain any required approvals of governmental authorities applicable to use of investigational drugs
- I will obtain the informed consent of the patient or patient's legally acceptable representative in accordance with applicable laws and regulations before giving the first dose of the investigational drug to the patient
- I **will** ensure that the informed consent authorizes the transfer of study data to Context or its representatives for research or regulatory purposes
- I will inform my patient of the risks associated with the investigational drug, including that it has not been approved in this country, prior to the first administration of the investigational drug
- I will notify and/or obtain approval from the institutional review board/independent ethics committee regarding the use of the investigational drug for the patient specified in the request, if required by applicable laws and regulations or institutional requirements
- I confirm that I have asked and obtained consent from the patient to the collection and use of any personal data and communication of such data to regulatory authorities to the extent necessary to comply with local laws
- I acknowledge that I am responsible for reporting all adverse events associated with use of the investigational drug, regardless of causality to Context. I will notify Context within 24 hours of my becoming aware of any fatal or immediately life- threatening adverse event and within 15 days of my becoming aware of all other adverse events
- I will maintain the confidentiality of information provided about the investigational drug and disclose or disseminate such information only as required by law or regulation or as authorized by Context
- I agree that Context may use data and results generated as a result of the administration of the investigational drug to patients for any purpose in accordance with applicable laws, and that Context will own all resulting patent or other intellectual property rights
- I will adhere to all applicable local laws and regulations
- I will inform Context when the patient specified in the request is no longer receiving treatment with the requested investigational drug
- I will provide Context any written summaries that are provided to local regulatory authorities at the conclusion of treatment with the investigational drug, including adverse events
- I will submit any publication material to Context prior to submission, for review and approval
- I certify that I have read, understood and accept the above acknowledgments.
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_____	_____
Name	Institution
_____	_____
Signature	Date

Once completed, email the request form to info@contexttherapeutics.com