

Single Patient Expanded Access/Compassionate Use Guide

Single Patient Expanded Access is an investigational treatment pathway for a patient with a **serious or immediately life-threatening illness or condition with no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.**

Single Patient Expanded Access situations are based on urgency for use - **Emergency** or **Non-Emergency** - and type of investigational product – **Drug** or **Device**. An Emergency situation requires a patient to be treated before an IRB submission can be made. This is generally an acute medical emergency where time to treat a patient is critical (within hours or a day) and no comparable or satisfactory alternative therapy option is available. However, even in an emergency use situation, it is best practice to contact the IRB before use. Additionally, there are regulatory requirements before and after each category of Single Patient Expanded Access use as described in the table below.

	Emergency	Non-Emergency
Drug	<ul style="list-style-type: none"> ❖ FDA authorization obtained prior to use. ❖ Drug manufacturer authorization obtained prior to use. ❖ Clearance from institution/site obtained prior to use. ❖ Because of the immediate need to use the drug, there is no time to obtain IRB approval /concurrence prior to use. Treating physician submits Single Patient Expanded Access Form to IRB within 5 days of use. ❖ Informed consent from patient or legal representative (LAR) obtained prior to use OR attestation from independent physician that criteria for waiver/exception from requirements of informed consent in an emergency situation are met is obtained prior to use. ❖ Treating physician submits Closure Application to IRB after treatment and follow-up concludes to describe status of patient. 	<ul style="list-style-type: none"> ❖ FDA authorization obtained prior to use. ❖ Drug manufacturer authorization obtained prior to use. ❖ Clearance from institution/site obtained prior to use. ❖ IRB approval/concurrence obtained prior to use. ❖ Informed consent of patient or LAR obtained prior to use. ❖ Treating physician submits Amendment/Reportable Event Application(s) to IRB, as applicable (for example, treatment plan changes, new risks, reportable events). ❖ If patient treatment extends beyond 1-year IRB approval/concurrence, treating physician submits a request for Continuing Review to IRB. ❖ Treating physician submits Closure Application to IRB after treatment and follow-up concludes to describe status of patient.
Device	<ul style="list-style-type: none"> ❖ Independent attestation from an independent physician that criteria for emergency use expanded access are met is obtained prior to use. ❖ Device manufacturer authorization obtained prior to use. ❖ Clearance from institution/site obtained prior to use. ❖ Because of the immediate need to use the device, there is no time to obtain IRB approval /concurrence prior to use. Treating physician submits Single Patient Expanded Access Form to IRB within 5 days of use. ❖ Informed consent from patient or LAR obtained prior to use OR attestation from independent physician that criteria for waiver/exception from the requirements of informed consent in an emergency situation are met is obtained prior to use. ❖ If there is an IDE for the device, the IDE sponsor must notify the FDA of the emergency use within 5 days through submission of an IDE Report. If no IDE exists, the treating physician submits a follow-up report to the FDA within 5 days on the use of the device. ❖ Treating physician submits Closure Application to IRB after treatment and follow-up concludes to describe status of patient. 	<ul style="list-style-type: none"> ❖ FDA authorization is obtained prior to use. (If there is an IDE for the device, the IDE sponsor submits an IDE supplement requesting approval for compassionate use. If there is no IDE for the device, a compassionate use request for a single patient is submitted to the FDA by the physician or manufacturer.) ❖ Independent attestation from an independent physician that criteria for expanded access are met is obtained prior to use. ❖ Device manufacturer authorization obtained prior to use. ❖ Clearance from institution/site obtained prior to use. ❖ IRB approval/concurrence obtained prior to use. ❖ Informed consent of patient or LAR is obtained prior to use. ❖ Treating physician submits follow-up report to FDA within 45 days of use. ❖ Treating physician submits Amendment/Reportable Event Application(s) to IRB, as applicable (for example, treatment plan changes, new risks, reportable events). ❖ If patient treatment extends beyond 1-year IRB approval/concurrence, treating physician submits a request for Continuing Review to IRB. ❖ Treating physician submits Closure Application to IRB after treatment and follow-up concludes to describe status of patient.

Please contact Castle IRB with questions about Single Patient Expanded Access at **888-442-2472** or irbteam@castleirb.com.

Also consider that the FDA maintains the following resources and guidance for treating physicians and industry:

- *Expanded Access to Investigational Drugs for Treatment Use — Questions and Answers Guidance for Industry*
- *Emergency Use of an Investigational Drug or Biologic: Guidance for Institutional Review Boards and Clinical Investigators*
- *Expanded Access | Information for Physicians*
- *Expanded Access for Medical Devices*