SOP Addendum
SOP SC 502 RESEARCH WITH TEST ARTICLES
3.6 Emergency Use of Investigational Article or Product
3.8.4 Review of Treatment/Compassionate Use Protocols

Upon receipt of the protocol utilizing a treatment use IND/IDE or compassionate use IDE (or can be referred to as an expanded access application), an IRB Administrator with the assistance of the Director, Associate Director, Assistant Director or Senior IRB Administrative staff determines the appropriate level of review. An IRB Chair will be consulted as needed. Such type of protocol applications require convened IRB review, given the treatment/compassionate use may pose greater than minimal risk, unless an emergent situation presented itself. The IRB staff will consider whether there is adequate time and resources to allow for the protocol to be scheduled and reviewed by the appropriate convened IRB without negatively affecting a potential benefit to a patient.

The level of review required for exception requests (expedited or convened) is dependent upon the following factors:

- The time sensitivity of the request
- The level of risk involved in both the treatment/compassionate use itself
- Whether the treatment/compassionate use is thought to be in the best interest of the subject
- Whether the treatment/compassionate use holds out the prospect of direct benefit to the subject
- Whether the risk/benefit ratio specifically related to the treatment/compassionate use request is favorable

The following expanded access applications may be eligible for physician IRB Chair review:

- The treatment/compassionate use is time sensitive
- The treatment/compassionate use is in the best interest of the patient and/or the prospect of direct benefit exists
- The risk/benefit ratio for the proposed treatment/compassionate use request is favorable

The following expanded access applications may require convened IRB review:

- It is unclear whether the treatment/compassionate use is in the subject's best interest or whether there is the prospect of direct benefit to the subject
- It is unclear whether the risk/benefit ratio is favorable
- The treatment/compassionate use is not time sensitive and there is sufficient time to allow convened IRB review to occur

When convened IRB review is not utilized, individuals conducting expedited review will contact the Director or IRB Chair to request a consultant’s review as needed. An IRB Chair is responsible for reviewing and approving the protocol.

Protocols requiring convened review will be scheduled for the appropriate convened IRB.

The IRB does not require formal continuing review submissions for annual renewals of expanded access protocols that meet the requirements needed for protocols determined to be greater than minimal risk research (i.e. progress report, monitoring summary, etc.). Annual reports for expanded access protocols may be provided at the end of the compassionate/treatment use if the report exists. As the treating
physician is required to submit a summary report to the FDA and the sponsor, if applicable, the treating physician may provide this report at the end of the compassionate/treatment use.