# [Title]

# Introduction/Background/Rationale

# *Summary of the drug/biologic, any applicable data or publications or ongoing trials of the drug/biologic.*

# Disease or Condition for Expanded Access

# Patient Eligibility (if applicable)

# *Note any criteria for e.g. lab parameters, no signs or symptoms of infection, prohibited medications etc.*

# Process of Informed Consent

# ***Obtain Informed Consent from patient or their legally authorized representative per 21 CFR Part 50.*** *Refer to 21 CFR Part 50.23 for exception from general requirements.*

# Subject ID Assignment (if applicable)

# Treatment and Assessments

# *Treatment is generally limited to a single course of therapy for a specified duration unless FDA expressly authorizes multiple courses or chronic therapy. If for example the desire is for the patient to continue as long as they are benefiting or until disease progression this must be expressly spelled out. Treatment Plan (Including the dose, route and schedule of administration****,*** *premedications and supportive care****, planned duration****, and monitoring procedures. Also include modifications to the treatment plan in the event of toxicity.)*

# Serious Adverse Event Reporting

# *Include any special considerations. For example, if there are planned admissions or other know considerations that would typically be SAEs, but would not be considered an SAE make note of any exceptions.*

# Follow-up Plan

# *Describe both the short- and long-term follow-up plans.*