REPORTING REQUIREMENTS FOR COMPASSIONATE USE DRUGS

SUBMISSIONS AND TIMING	ACTION	DOCUMENTATION
Mandatory Safety Reports for Fatal or Life-Threatening Events *As soon as possible but no later than within 7 days of occurrence*	Report unexpected fatal or life-threatening suspected adverse reactions to FDA Report to the drug manufacturer	1. FDA form 1571 (check initial or follow up IND Safety Report in Section 11) 2. FDA form 3500A
Mandatory Safety Reports for Other Adverse Events *As soon as possible but no later than within 15 days of occurrence*	Report serious and unexpected suspected adverse reactions Report to the drug manufacturer	1. FDA form 1571 (check initial or follow up IND Safety Report in Section 11) 2. FDA form 3500A
IND Application Amendments *At any time during the IND application life cycle*	Submit an Amendment to the IND application if there are any changes to the information sent in the initial IND application submission	1. FDA form 1571 (check Section 11 for all amendments that apply) 2. Application's Amendment with explanation of the changes to the application and additional data, when relevant 3. FDA form 1572 (required only if a new investigator is added)
IND Treatment Results Summary *Following completion of the IND treatment*	Provide FDA with a written summary of the results of the investigational treatment Report to the drug manufacturer Please share the outcomes with the Compassionate Use Navigator	1. FDA form 1571 2. Cover letter referring to the written summary report (include a request to close the IND application, if applicable) 3. Written report of the results of treatment, patient response, all adverse effects, and drug disposition.
IND Application Annual Report (if IND application remains active) *Within 60 days of the anniversary date when the application went into effect*	Submit IND application Annual Report	1. FDA form 1571 (check Annual Report in Section 11) 2. An update for all information sent in the initial submission for the IND application to include: (1) summary of treatment results, (2) safety findings, (3) drug disposition, and (4) any other changes including non-clinical or clinical information, as relevant.