Therapeutics and Pharmacology Case Report Form

Date that this CRF was filled out: _____

Name of Laboratory/PI: _____

Name of person filling out CRF: _____

Project name/Identifier: _____

Animal ID or Study ID (as applicable): _____

Type of model system:

- Mammalian systems (e.g., rodents, other mammals): _____
- Non-mammalian systems (e.g., *Drosophila*, zebrafish): _____

Type of study:

- Anesthetized: _____
- Non-anesthetized: _____

Endpoint of study:

- Pre-defined time point: _____
- Seizure-induced sudden death: _____
- Other _____

CDE	**Data Collected**
Type of therapeutic administered (anti-seizure medication)	☐ Small molecule ☐ Biologic ☐ Anti-sense oligonucleotides ☐ Dietary therapies / metabolic therapy ☐ Neurostimulation ☐ Non-traditional medication ☐ Other _____
Name of therapy administered; insert details on: • Name (brand/chemical) • Lot number • Batch number • Supplier Catalog information	_____ _____ _____ _____
Dose	
Frequency of administration	
Method of administration	☐ Intraperitoneal (IP) ☐ Oral gavage ☐ In food or water ☐ Intramuscular (IM) ☐ Intravenous (IV)

	☐ Subcutaneous (SC) ☐ Intrathecal ☐ Bath immersion ☐ Other _____
Timeline: when in relation to seizure onset or induction is drug administered	
Name of vehicle or control, if applicable	
Mechanism of action	
How was mechanism of action confirmed, i.e. antagonist administration	
Type of dietary therapy	☐ Classic Ketogenic diet ☐ Low glycemic index therapy ☐ Modified Atkins ☐ Other _____
Parameters of dietary therapy	
Types of Neurostimulation A. Site of stimulation B. General parameters i. Duration of stimulation ii. Strength iii. Time	_____ _____ _____ _____
Overall health A. Weight B. Appearance (add in standardized terms)	_____ ☐ Appeared overall healthy ☐ Weak/sluggish ☐ Moribund
Onset of therapeutic effect (time after drug administration)	
Offset of therapeutic effect	
Behavioral seizures	☐ Reduction; ☐ Cessation; ☐ No effect;☐ Other _____
Electrographic seizures	☐ Reduction; ☐ Cessation; ☐ No effect; ☐ Other _____
What seizure features were affected?	☐ Frequency; ☐ Duration; ☐ Other _____
Prevention of respiratory arrest	☐ Yes; ☐ No; ☐ Unknown

Prevention of respiratory abnormalities	☐ Yes; ☐ No; ☐ Unknown
Prevention of cardiac abnormalities	☐ Yes; ☐ No; ☐ Unknown
Extension of survival?	☐ Yes; ☐ No; ☐ Unknown
Comments:	
Additional/Adverse Effects	
Known toxicology?	☐ Yes; ☐ No; ☐ Unknown
Motor Effects	
Anesthesia (total loss of feeling or sensation, unresponsive to tail pinch and tapping of the eye)	☐ Yes; ☐ No; ☐ Unknown
Ataxia (lack of voluntary coordination of muscle movements, can include wobbly gait)	☐ Yes; ☐ No; ☐ Unknown
Loss of righting reflex (unable to turn over when placed in a dorsal recumbent position)	☐ Yes; ☐ No; ☐ Unknown
Unable to grasp rotarod (inability to hold on to rotarod in order to begin test)	☐ Yes; ☐ No; ☐ Unknown
Minimal motor impairment	☐ Yes; ☐ No; ☐ Unknown
Loss of muscle tone (soft, with low muscle tone)	☐ Yes; ☐ No; ☐ Unknown
Sedation (very calm or appear to be sleeping, but will respond to external stimuli)	☐ Yes; ☐ No; ☐ Unknown
Altered startle response	☐ Yes; ☐ No; ☐ Unknown
Seizure Effects	
Continuous seizure activity	☐ Yes; ☐ No; ☐ Unknown
Clonic seizures (muscle convulsions of the forelimbs and/or hindlimbs)	☐ Yes; ☐ No; ☐ Unknown
Neurological Manifestations	
Intense, repeated jumping straight up	☐ Yes; ☐ No; ☐ Unknown
Myoclonic jerks (non-rhythmic muscle twitch, jerk, shake or spasm)	☐ Yes; ☐ No; ☐ Unknown
Wild running (frantic running)	☐ Yes; ☐ No; ☐ Unknown
Writhing (a stretch, tension to one side, extension of hind legs, contraction of the abdomen, or twisting of the trunk)	☐ Yes; ☐ No; ☐ Unknown

Hyperactivity (increased velocity of movement, faster motion than typical)	☐ Yes; ☐ No; ☐ Unknown
Severe tremors (strong rhythmic muscle contraction, shaking movements in the limbs or body leading to complete or near incapacitation)	☐ Yes; ☐ No; ☐ Unknown
Exophthalmos (eye bulging)	☐ Yes; ☐ No; ☐ Unknown
Tremors (rhythmic muscle contraction, shaking movements in the limbs or body)	☐ Yes; ☐ No; ☐ Unknown
Muscle spasms (continuous or intermittent muscle contraction or rigidity)	☐ Yes; ☐ No; ☐ Unknown
Wet dog shakes (a brief, ~1 second shaking of entire body. not restricted to single body part)	☐ Yes; ☐ No; ☐ Unknown
Stretching and rolling (extension/elongation of the body; rolling onto one side with or without completely exposing the ventral body surface)	☐ Yes; ☐ No; ☐ Unknown
Retropulsion (backward locomotion or backward circling)	☐ Yes; ☐ No; ☐ Unknown
Arching (arching of the back)	☐ Yes; ☐ No; ☐ Unknown
Hypoactivity (decreased velocity, slower-than-typical motion)	☐ Yes; ☐ No; ☐ Unknown
Physiological Manifestations	
Diarrhea (loose, watery stool)	☐ Yes; ☐ No; ☐ Unknown
Salivation (noticeable saliva outside the mouth)	☐ Yes; ☐ No; ☐ Unknown
Piloerection (hairs become erect and bristle due to hair follicle contraction i.e., goose bumps)	☐ Yes; ☐ No; ☐ Unknown
Hyperesthesia (increase in sensitivity for all senses, i.e., jumping at noises, running or jumping when touched)	☐ Yes; ☐ No; ☐ Unknown
Vocalizations (noises audible to humans)	☐ Yes; ☐ No; ☐ Unknown
Excessive grooming (intense, excessive or disproportionate body	☐ Yes; ☐ No; ☐ Unknown

cleaning; may be restricted to specific body parts, with or without visible signs of tissue damage)	
Urinary staining (pigmented urine)	☐ Yes; ☐ No; ☐ Unknown
Bloody urine (bright red urine)	☐ Yes; ☐ No; ☐ Unknown
Cold tail (tail feels cold when touched)	☐ Yes; ☐ No; ☐ Unknown
Cold to the touch (animal's body feels colder than typical - more severe than cold tail, above)	☐ Yes; ☐ No; ☐ Unknown
Changes in heart rate	☐ Yes; ☐ No; ☐ Unknown
Other toxic effect	
Comments:	

Abbreviations: CRF: Case Report Form; PI: Principal investigator.

Instructions: Please check boxes where applicable. If none of the predetermined options is appropriate, use the default space to specify your answer. This form is to be filled in for one individual animal, unless otherwise specified.

Please refer to more extensive CRF where suitable, as developed by the ILAE/AES Joint Translational Task Force:

Report on preclinical Core CDEs
https://onlinelibrary.wiley.com/doi/10.1002/epi4.12234
Report on preclinical neurobehavioral CDEs
https://onlinelibrary.wiley.com/doi/10.1002/epi4.12236
Report on preclinical physiology CDEs
https://onlinelibrary.wiley.com/doi/10.1002/epi4.12261
Report on preclinical pharmacology model CDEs
https://onlinelibrary.wiley.com/doi/10.1002/epi4.12254
Report on preclinical EEG CDEs
https://onlinelibrary.wiley.com/doi/10.1002/epi4.12260