**Therapeutics / 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:**

**Type of study:**

* Anesthetized / Non-anesthetized
* Endpoint of study
* Pre-defined time point
* Death
* Other

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |
| --- | --- |
| **CDE** | **Data Collected** |
| Type of therapeutic administered | ☐ Antiseizure medication;  ☐ Anti-sense oligonucleotides;  ☐ Dietary therapies / metabolic therapy;  ☐ Neurostimulation;  ☐ Non-traditional medication  ☐ Other |
| If other type of therapeutic, specify |  |
| Name of therapy administered |  |
| Dose |  |
| Frequency of administration |  |
| Method of administration | ☐ Intraperitoneal (IP);  ☐ Oral gavage;  ☐ In food or water  ☐ Intramuscular (IM);  ☐ Intravenous (IV);  ☐ Subcutaneous (SC);  ☐ Intrathecal  ☐ 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 |
| If other type of dietary  therapy, describe |  |
| Parameters of dietary therapy |  |
| Types of Neurostimulation   1. Site of stimulation 2. General parameters 3. Duration of stimulation 4. Strength 5. Time |  |
| Overall health   1. Weight 2. Appearance (add in standardized terms) | ☐ Appeared overall healthy;  ☐ Weak/sluggish;  ☐ Moribund |
| Onset of therapeutic effect (time after drug administration) |  |
| Offset of therapeutic effect |  |
| Clinical 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 |
| Additional 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 |
| Sedated (very calm or appear to be sleeping, but will respond to external stimuli) | ☐ Yes; ☐ No; ☐ Unknown |
| Continuous seizure activity | ☐ Yes; ☐ No; ☐ Unknown |
| Clonic seizures (muscle convulsions of the forelimbs and/or hindlimbs) | ☐ Yes; ☐ No; ☐ Unknown |
| 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 |
| Myoclonic jerks (non-rhythmic muscle twitch, jerk, shake or spasm) following investigational compound administration but before the induction of a seizure test | ☐ 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 recurrent 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 |
| 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 cleaning; may be restricted to specific body parts, with or without visible signs of tissue damage) | ☐ Yes; ☐ No; ☐ Unknown |
| 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 |
| Other Toxic Effect |  |
| **Comments:** | |

Additional considerations:

1. Perhaps grouping responses at autonomic, neurobehavioral, physiological, etc, would provide an easier format to follow. Thoughts?
2. Should we also include hepatic, renal and/or GI (adverse) effects of therapeutics?