Owner Informed Consent

Neural Progenitor Cells for Dogs with Chronic Severe Thoracolumbar Spinal Cord Injuries

I understand that the veterinarians at CSU are engaged in research into the nature and treatment of chronic spinal cord injury in dogs. The detailed procedures of the stem cell injections with subsequent monitoring with MRI and electrodiagnostic examinations have been explained to me by:

Dr. ___________________________ on __________________________.

As part of this particular study, I understand the following:

- My dog must have a diagnosis of chronic thoracolumbar spinal cord injury, confirmed via MRI, in order to be eligible to participate in this study, and be negative for deep pain perception for at least 4 weeks, but no longer than 12 weeks.
- The primary purpose of this study is to determine whether canine neural progenitor cells (nerve stem cells) generated in tissue culture from stem cells of a healthy dog are safe and effective when used to treat dogs with severe chronic spinal cord injury.
- The study in dogs is based on results of promising studies in rodent models of spinal cord injury using similar nerve stem cells.
- However, it is not known whether such stem cells are either safe or effective in dogs with spinal cord injury, as these exact stem cells have not been used previously in dogs. Related stem cells have been used in dogs with spinal cord injury safely, though any treatment effects observed were small. However, no studies have researched the safety and efficacy of neural progenitor cells in dogs with chronic spinal cord injury.
- The potential risks of this type of stem cell therapy are that the cells may elicit a local immune response at the spinal cord injury site when injected in my dog, or that the stem cells may form a tumor at their site of implantation. Based on studies in rodent models, we believe the risk of either side effect is very small, but cannot be ruled out.
- Because this stem cell treatment is still very experimental, there is no guarantee that my dog will benefit from this treatment.
- My dog will be treated by a group of veterinarians specializing in clinical neurological and neurosurgical conditions and treatments.
- The potential side effects of anesthesia, including abnormal reaction to anesthetic agents, organ failure, obstructed airway, regurgitation, aspiration of vomitus, nerve damage, equipment malfunction and death, have been explained to me and I understand the risks.
• The potential side effects of the stem cell injections have been explained to me (above) and I understand the risks.

• Alternate (non-study) treatment options, including physical therapy, have been discussed and I understand the relative benefits of those treatments.

• I understand that if my dog is found eligible for the study, for the study period of 48 weeks, the costs listed below will be covered by the study. These costs will include the costs of three re-check examinations (12, 24 and 48 weeks post injections), pre-anesthetic bloodwork and thoracic radiographs, one MRI study before the stem cell injection (if eligibility confirmed) and one MRI examination 12 weeks after the stem cell injection, stem cell injections (including fluoroscopy and supplies), 24 hours of hospitalization, medication associated with immune suppression (cyclosporine) for 24 weeks, and 4 electrodiagnostic studies, including anesthesia.

• I understand that I am responsible for the initial MRI, pre-anesthetic bloodwork, thoracic radiographs and anesthesia if the MRI reveals that my dog is not eligible. I also understand that I am responsible for any additional costs associated with my dog’s condition and/or treatment after the study period and for any costs associated with conditions unrelated to the original spinal cord injury.

• I give my permission to publish data obtained from this study for the benefit of the scientific community. I understand that neither my dog nor I will be identified individually.

• I agree to present my pet for all requested recheck examinations as described above.

• I may withdraw my dog from this study at any time without penalty.

• The veterinarian in charge may withdraw my dog from this study if he/she determines that my dog is adversely affected by the stem cell injection.

• I may discuss this procedure and the clinical trial with my own family veterinarian and ask his/her advice.

As a result of discussion with Dr. ________________________, and after reading the above, I voluntarily consent to participate in this project and will follow the instructions of the veterinarians-in-charge, as it pertains to therapy and follow-up procedures.

Signed: ___________________________________________  Date ____________________

Owner or authorized agent of the owner

Witnessed By: _____________________________________  Date ____________________

Colorado State University
James L. Voss Veterinary Teaching Hospital
Department of Neurology and Neurosurgery
Phone: (970) 297-4543