

## APRIL'S TOUGH CASE

In January, the US Food and Drug Administration granted California's Geron Corporation permission to launch the world's first study of a human embryonic stem cell (hESC)-based therapy in human beings. This is a small Phase I multi-center trial designed to establish the safety of hESC-derived oligodendrocyte progenitor cells (GRNOPCI) and to identify any potential adverse effects. The target population for the study are patients with "complete" American Spinal Injury Association (ASIA) grade A subacute thoracic spinal cord injuries (patients paralyzed from the waist down) occurring eight to fourteen days prior to the study.

According to Geron's announcement:

*GRNOPC1, Geron's lead hESC-based therapeutic candidate, contains hESC-derived oligodendrocyte progenitor cells that have demonstrated remyelinating and nerve growth stimulating properties leading to restoration of function in animal models of acute spinal cord injury (Journal of Neuroscience, Vol. 25, 2005). "The neurosurgical community is very excited by this new approach to treating devastating spinal cord injury," said Richard Fessler, M.D., Ph.D., professor of neurological surgery at the Feinberg School of Medicine at Northwestern University. "Demyelination is central to the pathology of the injury, and its reversal by means of injecting oligodendrocyte progenitor cells would be revolutionary for the field. If safe and effective, the therapy would provide a viable treatment option for thousands of patients who suffer severe spinal cord injuries each year." <http://www.geron.com/grnopc1clearance/grnopc1-pr.html> (Accessed 4/24.2009).*

Questions for discussion

1. How does clinical research using hESC-based therapies differ, if at all, from other cell-based therapies?
2. Geron's study has yet to win IRB approval. What special issues of informed consent does this study raise? How might the IRB best address them?
3. How does the requirement that this novel therapy take place within 14 days after injury raise additional ethical (and scientific) concerns?