

## James & Esther King Biomedical Research Program

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*Neurosurgery  
University of South Florida*

*2009 Program  
Bridge (1-year project)*

**Project Title:** Preclinical STEPS Consortium

**Project Summary:** Bone marrow derived progenitor cells have properties that make them highly suitable as donor cells for restorative therapy. Theradigm, Inc., and SanBio, Inc., have the proprietary rights to specific progenitor cells derived from bone marrow. Our research team has a collaborative relationship with these companies, which have developed manufacturing techniques to make these cells available for clinical use. These companies will supply these cells to us. Our combined preliminary data in rodents indicate that transplantation of these cells stands as a promising therapy for ischemic stroke. In order to develop the utility of these cells fully for clinical stroke, we propose a translational protocol consisting of milestone-driven experiments, which will serve as the preclinical basis for proceeding with transplantation of these cells in ischemic stroke patients. This grant establishes the Preclinical STEPS (Stem cell Therapeutics as an Emerging Paradigm for Stroke) Consortium, comprised of three expert stroke laboratories (Drs. Borlongan, Chopp, and Steinberg), a Data Coordination Center under the supervision of Dr. Lu, and a clinical steering committee headed by two stroke/cell therapy physician-scientist experts, Drs. Hess and Kondziolka. The overarching goal is to provide the optimal cell transplantation regimen (including dose, route, and timing post-stroke) for each bone marrow derived progenitor cell type that will produce an effective and safe cell therapy in rodent models of adult ischemic stroke. Although these cell treatments have demonstrated therapeutic efficacy in individual laboratories, it is imperative for clinical translation that these cells be tested in multiple models of focal stroke, in two species, and in multiple laboratories.

Because stroke is a leading cause of death and disability in the U.S. and around the world, and with a very limited treatment option, the preclinical demonstration of efficacy and safety of cell therapy, along with the Stroke Therapy Academic Industry Roundtable (STAIR) and STEPS guidelines, should enhance the success of this experimental treatment in the clinic.