



# TISCH MS

RESEARCH CENTER OF NEW YORK

Saud A. Sadiq, MD  
Director  
Senior Research Scientist

RESEARCH SCIENTIST  
Violaine Harris, PhD

ASSISTANT RESEARCH SCIENTISTS  
Massimiliano Cristofanilli, PhD  
Ying Liu, MD, PhD  
Fozia Mir, PhD  
Andre Mueller, PhD

RESEARCH ASSOCIATE  
Irene Jarchum, PhD  
Tamara Vyshkina, PhD

SENIOR STAFF ASSOCIATE  
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STAFF ASSOCIATES  
Kristi Clark, MS  
Boxun Xie, MS

RESEARCH ASSISTANTS  
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Lena Bell, BA  
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Barbara Cymring, BA  
Deirdre Dulak, BS  
Eva Franzova, BS  
Daniel Koffler, BA  
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Karen Sheikh, BA  
Bo Hyung Yoon, BS

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Xinhe Liu, MEd

LABORATORY TECHNICIAN  
Michael Boatwright

CLINICAL RESEARCH  
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Dorothy Kurdyla, RN, MSN  
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Development Manager

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Media Inquiries: Pamela Levin, RN  
646-557-3891, [plevin@imsmp.org](mailto:plevin@imsmp.org)

## FDA APPROVES STEM CELL CLINICAL TRIAL FOR MULTIPLE SCLEROSIS

**New York, NY-** August 14, 2013- The Tisch MS Research Center of New York announced today that it has received Investigational New Drug (IND) approval from the Food and Drug Administration (FDA) to commence a Phase 1 trial using autologous neural stem cells in the treatment of multiple sclerosis (MS). MS is a chronic human autoimmune disease of the central nervous system that leads to myelin damage and neurodegeneration and affects approximately 2.1 million people worldwide.

“To my knowledge, this is the first FDA-approved stem cell trial in the United States to investigate direct injection of stem cells into the cerebrospinal fluid of MS patients, and represents an exciting advance in MS research and treatment,” said Dr. Saud A. Sadiq, Senior Research Scientist at Tisch MS Research Center of New York and the study’s principal investigator.

The groundbreaking study will investigate a regenerative strategy using stem cells harvested from the patient’s own bone marrow. These stem cells will be injected intrathecally (into the cerebrospinal fluid surrounding the spinal cord) in 20 participants who meet the inclusion criteria for the trial. This will be an open label safety and tolerability study. All study activities will be conducted at the Tisch MS Research Center and affiliated International Multiple Sclerosis Management Practice (IMSMP).

The clinical application of autologous neural progenitors in MS is the culmination of a decade of stem cell research conducted by a dedicated team of scientists headed by Dr. Sadiq and by Dr. Violaine Harris, Research Scientist at Tisch MS Research Center.

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Preclinical testing found that the injection of these cells may decrease brain inflammation and promote myelin repair and/or neuroprotection. “This study exemplifies the Tisch MS Research Center’s dedication to translational research and provides a hope that established disability may be reversed in MS,” Dr. Sadiq noted.

Participants will undergo a single bone marrow collection procedure, from which mesenchymal stem cell-derived neural progenitor cells (MSC-NPs) will be isolated, expanded and tested prior to injection. Participants will receive three rounds of injections at three month intervals. Safety and efficacy parameters will be evaluated in all participants through regular follow-up visits.

For more information on this study visit: [www.tischms.org](http://www.tischms.org)

#### **ABOUT TISCH MS RESEARCH CENTER OF NEW YORK**

For over twenty years, Dr. Saud A. Sadiq has believed that combining excellence in clinical care with innovative research targeted at finding the cure for multiple sclerosis would set an exemplary standard in the treatment of MS patients. Today, the Tisch MS Research Center of New York embodies this new model of healthcare, in which your doctor is also your researcher. Dr. Sadiq helps those with MS by conducting cutting-edge, patient-based research to ensure unparalleled care. The close relationship of the non-profit research center and its affiliated clinical practice (International Multiple Sclerosis Management Practice) enables the testing of new MS treatments and accelerates the pace at which research discoveries move from lab bench to bedside. The Tisch MS Research Center of New York aims to identify the disease trigger, optimize treatments for patients, and repair the damage caused by multiple sclerosis.

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