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NYSCF Calls For Faster FDA Review to Curb Stem Cell Tourism Citing Baby Born Using Mitochondrial Replacement Therapy Performed in Mexico

New York, NY (September 28, 2016) – A report in *The New Scientist* presents claims that the first baby was born in Mexico by a New York based doctor using mitochondrial replacement therapy, a technique pioneered and advanced by scientists at The New York Stem Cell Foundation Research Institute and colleagues in the United States and in the United Kingdom. This technique is currently unapproved for any use in the US.

"The development and timely review of new, high quality treatments for patients must be a top priority for the US. Without rigorous regulatory review and oversight in the US, many families and patients in need turn to clinics abroad where they undergo treatments that may not be subject to appropriate oversight," said Susan L. Solomon, CEO of the NYSCF Research Institute. "Our regulatory system can only work if it is timely and nimble enough to react to technological developments as they occur. This is a fast moving field that requires the full partnership of the FDA throughout the development of new treatments, technologies, and cures. The current federal funding challenges are a major problem for advancing all novel treatments in the US, not only mitochondrial replacement therapy."

"We can be optimistic about the fact that a mitochondrial replacement technique first used in human cells by us will likely be effective with FDA oversight," said Dr. Dieter Egli, NYSCF Senior Research Fellow, NYSCF – Robertson Investigator, and lead scientist in the development of the mitochondrial replacement technique. "Doctor and patient had to go elsewhere to perform a version of the groundbreaking treatment that was pioneered at NYSCF in the US. This is compounded by current laws that restrict federal funding and therefore the ability to broadly perform research and novel treatments in the field of stem cells and reproduction in the US."

Patients will continue to seek experimental treatments and therapies in the hope of cures. This stem cell tourism undermines the legitimate scientific efforts around the globe to incrementally work towards proven and safe treatments.

About The New York Stem Cell Foundation Research Institute

The New York Stem Cell Foundation (NYSCF) Research Institute is an independent organization accelerating cures and better treatments for patients through stem cell research. The NYSCF Research Institute employs over 45 researchers in New York, and is an acknowledged world leader in stem cell research and in developing pioneering stem cell technologies, including the NYSCF Global Stem Cell ArrayTM. Additionally, NYSCF supports over 86 researchers at other leading institutions worldwide through its Innovator Programs, including the NYSCF – Druckenmiller Fellowships and the NYSCF – Robertson Investigator Awards. NYSCF focuses on translational research in a model designed to overcome the barriers that slow discovery and replace silos with collaboration. For more information, visit www.nyscf.org