# Stem cell clinics and businesses are registering for-profit, pay-to-participate

July 19 2017

The Future Science Group (FSG) journal *Regenerative Medicine*, today announces the publication of a new Perspective article, in which Leigh Turner (University of Minnesota, MN, USA) discusses the urgent need for careful screening of clinical trials prior to registration with ClinicalTrials.gov in order to improve patient safety.

In the article, Turner discusses how U.S. clinics and international businesses that engage in direct-to-consumer advertising of purported stem cell treatments are successfully registering for-profit, pay-to-participate "studies" on the NIH registry and database, ClinicalTrials.gov. The registered studies often fail to disclose that individuals are charged to participate in clinical research and many of these studies have serious ethical and scientific flaws. Such shortcomings include blurring distinctions between evidence-based therapies and unproven investigational agents, using inappropriate inclusion and exclusion criteria, failing to conduct and publish adequate peer-reviewed pre-clinical research before administering stem cells to humans, and charging research subjects for cell-based interventions that are not supported by substantial evidence of safety and efficacy.

Using the ClinicalTrials.gov registry and other sources of information, Turner found that U.S. companies had successfully registered seven 'patient-sponsored,' 'patient-funded,' or 'self-funded' studies in which autologous stem cell interventions are administered to research subjects. Turner identified another eleven studies involving administration of autologous stem cells at U.S. locations in which study subjects are

charged to participate even though this information is not disclosed on ClinicalTrials.gov.

"I'm concerned that ClinicalTrials.gov, once thought to be a reliable and trustworthy source of information for patients and their loved ones, is now being used as a marketing platform by clinics engaging in direct-to-consumer promotion of so-called 'stem cell treatments'," stated Turner. "I have many reservations about the studies registered by such businesses.

"Patients have already been lured to stem cell clinics that use ClinicalTrials.gov to market unproven stem cell interventions. Furthermore, some patients have been injured after undergoing stem cell procedures at such businesses. Many individuals use ClinicalTrials.gov to find legitimate, well-designed, and carefully conducted clinical trials. They are at risk of being misled by study listings that lend an air of legitimacy and credibility to clinics promoting unproven and unlicensed stem cell interventions. Better screening is needed before more patients and research subjects are harmed. It's astonishing that officials at the NIH and US FDA haven't already done something to address this obvious matter of patient safety. Putting a disclaimer on the website isn't sufficient.

"My article identifies a serious problem and provides recommendations about what needs to be done, but there is much more for journalists, academic researchers, NIH officials and federal regulators to investigate," concluded Turner.

Adam Price-Evans, Commissioning Editor of *Regenerative Medicine* added, "With patients seeking out stem cell treatments becoming increasingly common, this article deals with a very timely issue and shines a light on the current landscape. With continuing advances in stem cell research and an increasing public accessibility to stem cell therapies,

full transparency is vital. With the ultimate goal of improving patient safety, hopefully this article will raise awareness and highlight an area that requires further attention."

"ClinicalTrials.gov, stem cells and pay-to-participate clinical studies" is published online ahead-of-print in *Regenerative Medicine*.

Provided by Future Science Group