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March 13, 2020

Patricia Flatley Brennan  
National Library of Medicine  
8600 Rockville Pike  
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Bethesda, MD 20894

**Comments regarding RFI: ClinicalTrials.gov Modernization,  
Notice Number: NOT-LM-20-003**

Dear Dr. Brennan,

On behalf of the International Society for Stem Cell Research (ISSCR), I write to share our comments regarding the modernization of the ClinicalTrials.gov database (NOT-LM-20-003). The ISSCR is the leading professional organization of stem cell researchers and represents more than 4,000 members in the US and around the world. Our members are scientists, clinicians, ethicists, and educators dedicated to the responsible advancement of stem cell research and its translation to the clinic. As you seek to modernize the ClinicalTrials.gov database, we urge you to prevent the database from being abused by clinics marketing unproven stem cell interventions.

Unscrupulous clinics use the ClinicalTrials.gov database to give the appearance that their approaches have undergone a formal and rigorous review and promote their treatments to patients searching for clinical trials. These clinics exploit the database with promotional and [false and misleading information](#), including links to sensational news stories and spurious claims that their interventions have a therapeutic benefit. The pollution of the ClinicalTrials.gov database with dubious listings negatively impacts the identification of and recruitment for legitimate trials. For a system that is designed to help patients, in its current form it increases the financial and physical risk to patients, including at least [one patient who was blinded by an unproven stem cell treatment found on ClinicalTrials.gov](#).

The NIH should create a mechanism for constant surveillance of the website to identify and warn the public about dubious listings that contain false and misleading information. This would

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make the database a safer place for patients and physicians to find information about legitimate clinical trials. Section 402(j)(5)(E)(iv) of the Public Health Service Act authorizes the NIH to include the following warning on any listing that contains false information, "information in the entry for this clinical trial was found to be false or misleading and therefore not in compliance with the law." This warning should be prominently displayed on any dubious listing that contains false or misleading information, or that offers a biologically implausible intervention for a heterologous indication (for example, adipose derived cells for Parkinson's disease, macular degeneration, or autism). While we understand that it may be impossible to review every listing, the database could have a flagging mechanism for the public to flag dubious listings for review by NIH, like Facebook's and Twitter's mechanisms for flagging inappropriate content.

The NIH could also improve the accuracy of ClinicalTrials.gov listings by requiring more information from registrants before listings are published in the database. During the submission process, registrants should be asked questions to validate whether their products are regulated by the US Food and Drug Administration (FDA). If the product requires an Investigational New Drug Application (IND), registrants should be required to submit proof of their IND and update their listing with the status of the IND (e.g., active, inactive, on clinical hold) within thirty days of any change. When registrations provide false or misleading responses to these questions, their trial listings should display the warning mentioned previously.

Thank you for considering our recommendations to improve the ClinicalTrials.gov database. If the ISSCR can clarify any of these views or be of assistance, please contact Eric Anthony, ISSCR's Director of Policy at [eanthony@isscr.org](mailto:eanthony@isscr.org).

Sincerely,

A handwritten signature in black ink, appearing to read 'D. Srivastava', with a long horizontal flourish extending to the right.

Deepak Srivastava, MD  
President, ISSCR  
President, Gladstone Institutes