



## NIH Request For Information (RFI) [NOT-OD-18-217](#)

### *Registration and Results Reporting Standards for Prospective Basic Science Studies Involving Human Participants*

As a follow-up to the July 20, 2018 NIH Notice ([NOT-OD-18-212](#)), NIH is requesting for input from stakeholders throughout the scientific research community regarding how best to implement the [NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information](#) for **prospective basic science studies involving human participants**.

- NIH is considering **prospective basic science studies involving human participants** to be those that overlap with both the definition of fundamental research and the definition of a clinical trial.

NIH wants to learn more about studies that meet the [NIH definition of a clinical trial](#) but are not defined as [applicable clinical trials](#), and also meet the [definition of fundamental research](#).

Specifically, NIH is requesting comments in the following areas:

- examples of prospective basic science studies involving human participants that pose the greatest challenges in meeting the registration and results information submission requirements at [ClinicalTrials.gov](#)
- strengths and weaknesses of potential alternative platforms that might function as conduits for timely registration and reporting of prospective basic science studies involving human participants
- additional data elements or modification to existing data elements that could be applied to [ClinicalTrials.gov](#) to better meet the needs of the public and of researchers in assuring timely registration and results information submission of prospective basic science studies involving human participants
- other existing reporting standards for prospective basic science studies involving human participants and how such standards would fulfill the aims described in the [NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information](#)

The **deadline** for submission of comments is **November 12, 2018**. Comments must be submitted electronically at: <https://grants.nih.gov/grants/rfi/rfi.cfm?ID=80>

For additional details, please review the August 10, 2018 NIH Notice [NOT-OD-18-217](#).