



## An update to the NIH Policy ([NOT-OD-18-212](#))

### *Delayed Enforcement and Short-Term Flexibilities for Some Requirements Affecting Prospective Basic Science Studies Involving Human Participants*

NIH is delaying enforcement of registration and reporting policies for prospective basic science studies involving human participants under [NOT-OD-16-149](#) through September 24, 2019.

- The delayed enforcement of registration and reporting is only applicable for prospective basic science studies that involve human participants; these studies **do not include** those for which there are specific applications towards products or processes in mind, such as phase 0 or phase 1 studies of candidate interventions.

NIH will provide leniency for applications submitted to the incorrect FOA based on the study type designation, as outlined below:

- NIH will delay enforcement of [its policy](#) that establishes the expectation that investigators will **register and report** their studies in [ClinicalTrials.gov](#). Through September 24, 2019, NIH will continue to expect registration and reporting for prospective basic science studies involving human participants, with additional flexibility to allow reporting on existing basic science portals, with the expectation that data will eventually be transported to [ClinicalTrials.gov](#).
- NIH has instituted a temporary period of leniency for applications submitted to an incorrect **FOA based on the study-type** designation. In this initial implementation phase (for due dates through September 24, 2019), NIH will not administratively reject any application for submission to an incorrect FOA based on study-type designation. Applications will be reviewed based on the review criteria of the FOA to which they are submitted, and for FOAs that specify that clinical trials are optional, based on the designation specified by the applicant.

NIH plans to issue FOAs specifically for prospective basic science studies involving human participants. A Notice of Intent to Publish these FOAs will be posted in October 2018. These announcements are scheduled to be published in November 2018 for due dates starting on January 25, 2019.

- NIH continues to expect [Good Clinical Practice \(GCP\)](#) training in accordance with [NOT-OD-16-148](#), for all personnel involved in the conduct, oversight, or management of prospective basic science studies involving human participants.
- There will be no change to the previously published [review criteria](#).
- All applications for prospective basic science studies involving human participants will require the **Human Subjects and Clinical Trial Information form**.

For additional details, please review the July 20, 2018 NIH Notice [NOT-OD-18-212](#).