

NIH Basic Science Studies and Clinical Trials: Next Steps

Actions	Details
For all trials that do not meet the definition of basic science, NIH will proceed with enforcement of the clinical trial policies as before	This will be reiterated in the NIH Guide Notices described below.
NIH Guide Notice which states that, for basic science studies, NIH will delay enforcement of policy on registration and reporting <u>posted in Federal Register on Sept 16, 2016</u>	NIH will delay enforcement through July 1, 2019.
NIH Guide Notice describing a flexible, lenient implementation of other policies for basic science studies	<ul style="list-style-type: none"> - Our goals are to enhance stewardship, transparency, ethical obligation to research participants. - These goals apply to all prospective interventional human trials. - NIH recognizes that not all trials occur within a clinical sphere (e.g. basic science trials, public health trials). - We will announce we are in an implementation phase in which we “monitor, refine, but not penalize” through July 1, 2019. - We will continue to expect registration and reporting for basic science trials, with added flexibility to allow reporting on existing basic science portals, and with the expectation that data will eventually be transported to clinicaltrials.gov, even if it is coming via another portal or reporting system.
Request For Information (RFI)	<ul style="list-style-type: none"> - NIH received a congressional directive to “consult with the basic research community to determine the reporting standards best suited to this kind of research.” - We will issue an RFI, open for 90 days, to address this.
Basic science parent funding opportunity announcement	<ul style="list-style-type: none"> - We will issue a Basic Science parent FOA for fundamental human studies that meet the NIH definition of clinical trial. - We will combine the transparency we all agree on with the recognition that these type of trials often occur outside of the clinical setting. - NIH commits to publishing the FOA no later than October 30, 2018.