



NIH Request For Public Comment ([NOT-OD-18-167](#))

Draft Protocol Template for Behavioral and Social Sciences

The National Institutes of Health (NIH) developed a template for NIH funded investigators to use in writing protocols for **behavioral and social sciences clinical trials**.

The [protocol template](#) was developed for these purposes:

- to use as a tool for communicating the science, methods and operations of a clinical trial
- to guide training and accountability of study staff
- to allow for efficient review by peers and oversight bodies
- to ensure adherence to the [International Conference on Harmonisation \(ICH\) E6 Good Clinical Practice \(GCP\)](#) guidelines
- to guide replication studies

Given the variations of intervention approaches and designs in the behavioral and social sciences, the NIH wants to encourage comments from a broad and diverse range of investigators on this draft protocol template.

Note: The template is a suggested format for clinical trials that are testing a behavioral or social intervention or experimental manipulation. Use of the final version of this standardized protocol template will be encouraged but will not be required.

The **deadline** for submission of comments is **October 11, 2018**:

- comments must be submitted electronically at: <https://osp.od.nih.gov/rfc-behavioral-social-sciences-studies/>

For additional details, please review the August 27, 2018 NIH Notice ([NOT-OD-18-167](#)).