



## NIH Releases SBIR/STTR Solicitations: Changes Small Businesses Need to Know

### Budget Waivers by Institute

Budget waivers are now listed in the omnibus NOFOs. Below is a summary of the budget waivers per institute.

NIH Institute / Center	Phase I Budget	Phase II Budget
NCI, NIA, NIAID, NIMH, NINDS, NIGMS, NCCIH	Up to \$700,000	Up to \$2,500,000–\$3,000,000
NEI, NHLBI, NHGRI, NIDCD, NIDA, NICHD, NINR, NIAAA, NIDDK	Up to \$400,000	Up to \$2,500,000–\$3,000,000
NIAMS, NIBIB, NIDCR, NIEHS, NIMHD, NLM, NCATS, ORIP, ORWH	Hardcap - \$323,090	Hardcap -\$2,153,927

Applicants should confirm the applicable limits directly with their target institute before finalizing budgets, as some institutes maintain the SBA guideline figures.

### Four Omnibus NOFOs Become Two

NIH has consolidated four separate Omnibus NOFOs into just two: PA-27-100 (SBIR) and PA-27-102 (STTR). Previously, NIH separated applications based on whether a clinical trial was required or not allowed. Both new Omnibus NOFOs accept applications regardless of whether a clinical trial is proposed (**Clinical Trial Optional**). An **important distinction is that** a regulatory plan is required if the submission has a clinical trial. Certain institutes still exclude clinical trials within the new NOFOs (e.g., all FDA components and NIAMS, NIDCR, NCATS, and ORIP in PA-27-100; NIAID, NIDDK, NIAMS, NIDCR, NIMHD, NCATS, and ORIP in PA-27-102).

### A Dedicated SBIR Phase IIB NOFO

Phase IIB has its own dedicated NOFO (PA-27-101), a significant structural shift for some institutes that previously allowed a Phase IIB submission under the omnibus.

- Participating NIH institutes are NEI, NHLBI, NIA, NIAAA, NIAID, NICHD, NIDDK, NIGMS, NIMH, NINDS, NIMHD, NCATS, NCI, ORIP, ORWH (co-funded).
- A clinical trial may be included except for NCATS and ORIP.
- A 100% matching fund is required.
- Award budgets range per institute. Some institutes are the Phase II hardcap while others are \$3M to \$4.5M and \$15M (NCI).



## Commercialization Readiness Program (CRP) NOFO

There is one CRP NOFO (PAR-27-098), with Clinical trial optional.

- Participating NIH institutes are NEI, NCI, NHLBI, NHGRI, NIA, NIAAA, NIAID, NIAMS, NIBIB, NICHD, NIDCD, NIDCR, NIDDK, NIEHS, NIGMS, NIMH, NINDS, NIMHD, NCATS, ORIP and ORWH (co-funded).
- Both SBIR and STTR mechanisms are allowed.
- Supports Technical Assistance and Late Stage Research
- Institutes that do not support clinical trials are NHLBI, NHGRI, NIAID, NIAMS, NIBIB, NIDCR, NIDDK, NIEHS, NCATS, ORIP.
- Award budgets range from \$500,000 to \$2,153,927 depending on the institute.

## Data Management and Sharing (DMS) Plan — Eliminated

In a notable reversal of prior NIH policy, the new solicitations explicitly state that a Data Management and Sharing Plan is **not applicable** for SBIR/STTR applications. Previously, a DMS Plan was required to be included in a submission. This requirement has been removed entirely across all new SBIR/STTR solicitations. SBIR/STTR recipients retain their existing right to the data generated under an award for up to 20 years after the award date.

## New Regulatory Plan Required for Clinical Trial Applications

Applications proposing a clinical trial must now include a standalone Regulatory Plan (2-page maximum). The Regulatory Plan must describe:

- The regulatory pathway being pursued
- A timeline for regulatory approval with discrete milestones
- Regulatory requirements to conduct a clinical trial
- Details of interactions with regulatory authorities

This new requirement is embedded across the Omnibus (PA-27-100, PA-27-102), Phase IIB (PA-27-101), and CRP (PAR-27-098) NOFOs. Reviewers will explicitly score the soundness of the Regulatory Plan under the Approach criterion.

## ORCID Now Required for All Senior/Key Personnel

All Senior/Key Personnel, including the PD/PI, must now be registered with ORCID and have their eRA Commons account linked to a valid ORCID ID prior to submission. This administrative requirement is new across all solicitations. Applicants who have not yet linked their ORCID ID to eRA Commons should do so promptly to avoid compliance issues.



**Entrepreneurial  
Training &  
Consulting**

18650 W Old US12  
Chelsea, MI 48118  
734-930-9741  
info@bbcetc.com | www.BBCetc.com

## **Commercialization Plan: Private-Sector Landscape Question**

Reviewers will evaluate whether the application addresses the current private-sector landscape in the proposed technical area, explains how the project differs from or complements existing commercial products or services, and justifies why federal support is warranted for projects that may duplicate well-funded private development.

## **New Administration Priorities Referenced**

The new solicitations direct applicants to consult several priority statements:

- **NIH Director's Statement of Priorities** — "Advancing NIH's Mission Through a Unified Strategy"
- **CDC Director's Statement of Priorities** — "CDC Priorities"
- **Make Our Children Healthy Again (MAHA) Strategy** — applicants are encouraged to align proposals with this strategy where applicable
- **FDA Mission Statement** — "FDA Mission"