NIH PRE-SUBMISSION CHECKLIST

What do you need to do before you submit a proposal
to NIH for the January 5, 2021 deadline.

1. Complete six registrations before submitting your application

There is more to a NIH SBIR/STTR than the research. The registration process alone may take six to eight weeks, so it's important to start as early as possible. All of these registrations must be completed prior to the application being submitted.

- Dun and Bradstreet Universal Numbering System (DUNS)
- Employer Identification Number (EIN)
- System for Award Management (SAM)
- Grants.gov (Register with Grants.gov)
- NIH's Electronic Research Administration System (eRA)
- Small Business Administration Company Registry (SBA)

2. Make sure you complete all of the following.

Leaving anything out will cause your submission to be rejected, no matter how great it is. So, make sure you have checked every box before sending in your proposal.

R&R Cover

☐ Cover Letter Attachment) *(now only required under special circumstances)*

R&R Other Project Information

☐ Project Summary/Abstract (< 30 lines)

☐ Project Narrative *(aka Public Health Relevance Statement*)

☐ Bibliography & References Cited

☐ Facilities & Other Resources

☐ Equipment

☐ Other attachments (only when specified in the FOA)

Senior/ Key Personnel Profile
☐ Biosketch for each Senior/Key person

R&R Budget
☐ Budget Justification (*for company*)

R&R Subaward Budget
☐ Budget Justification (*for sub award*)

Research Plan
☐ Introduction to Application (*Resubmissions only*)

☐ Specific Aims (max 1 page)

☐ Research Strategy (*6 pages Phase I, 12 pages Phase II and Fast-track*)

☐ Progress Report Publication List (*Renewal applications only*)

☐ Vertebrate Animals (*only if you are using Vertebrate Animals*)

☐ Select Agent Research (*if you are using anything hazardous*)

☐ Multiple PD/PI Leadership Plan (*if you have Multiple PIs*)

☐ Consortium/Contractual Arrangements (*if you have any subawards*)

☐ Letters of Support (*from consultants, subcontractors, strategic partners -- combined in one pdf*)

☐ Resource Sharing Plan(s) *(now required for almost all projects*)

☐ Authentication of Key Biological and/or Chemical Resources

☐ Appendix (*If the small business is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms the VCOC form is attached here.)*

SBIR/STTR Information Form:
☐ Commercialization Plan (*for Phase II and Fast-track proposals only*)

☐ Commercialization History (*If you have received previous SBIR Phase II awards*)

PHS Human Subjects and Clinical Trials information

The attachments below may or may not be required depending on whether your study involves Human Subjects or is a Clinical Trial. **Refer to Application Guide (Forms F) and Annotated Forms (Forms F) for detailed instructions."**

☐ Inclusion of women, minorities and children

☐ Recruitment and retention plan

☐ Study timeline

☐ Inclusion enrollment report(s)

☐ Protection of human subjects

☐ Data and safety monitoring plan

☐ Overall structure of the study team

☐ Statistical design and power

☐ Dissemination Plan

☐ Other Clinical Trial-related Attachments

PHS Assignment Request Form
Complete as appropriate.