



## **Pre-Submission Communications with BPN-Biologics Program Staff**

Please provide the following preliminary information and supporting data as instructed by the relevant Funding Opportunity Announcement (FOA) you plan to submit your proposal to:

[PAR-21-163](#): Blueprint Neurotherapeutics Network (BPN): Biologic-based Drug Discovery and Development for Disorders of the Nervous System ([UG3/UH3](#) Clinical Trial Optional)

[PAR-21-233](#): Blueprint Neurotherapeutics Network (BPN): Biologic-based Drug Discovery and Development for Disorders of the Nervous System ([U44](#) Clinical Trial Optional)

This information will enable us to determine your fit and eligibility for the proposed FOA and to provide you with further guidance on program scope, goals, and developing objectives.

Note: This form must be completed *six weeks* before application receipt date. Potential applicants interested in discussing an application with program staff are strongly encouraged to do so six weeks before receipt date. Any correspondence within six weeks of receipt date may only be completed by email.

Note for UG3/UH3 applicants: Applicants requesting \$500,000 or more in direct costs in any year must contact BPN-Biologics program staff at least 6 weeks (*12 weeks is strongly encouraged*) before submitting the application and follow the Policy on the Acceptance for Review of Unsolicited Applications that Request \$500,000 or More in Direct Costs as described in the SF424 (R&R) Application Guide. Budget justification will be needed to proceed to a discussion with senior leadership for Acceptance for Review of Unsolicited Applications.

### **Section 1: Submitter Information**

Submitter Name:

Institution:

PI Name and Institution (if different from submitter):

Primary Contact email address:

Team Management [List major collaborators and their expertise]:

### **Section 2: Proposed Study Information**

Do you plan to apply to UG3/UH3 Biologics FOA?

Yes

No

***OR***

Do you plan to apply to U44 BPN-Biologics FOA? (Note: U44 mechanism is for the SBIR program. If the primary PI/applicant is part of a small business, please select this FOA)

Yes            No

Expected Date of Submission:

Draft Title of Proposal:

Clinical Syndrome/Disorder:

Type of Proposed Modality:

If *Other*, please explain:

**Section 3: Information to Support Proposed Application**

Background and Supporting Data: (With a focus on explaining how the data meets the entry criteria for the PAR of interest; you may include relevant data and key citations that support your data)

Specific Aims:

Research Strategy:

Proposed budget by year:

Budget justification:

Have you had prior Regulatory Interactions/feedback?

Yes                  No

Is there availability of patient-derived cell lines?

Yes                  No                  Not Applicable

Please explain, if applicable:

Is there availability of animal model(s)?

Yes                  No                  Not Applicable

Please explain, if applicable:

Intellectual Property (Briefly explain your freedom to operate):

Is there any other relevant information you would like to add?