

# NEI SBIR/STTR REGULATORY ASSISTANCE PROGRAM APPLICATION FORM

## **Instructions:**

Review this application form carefully and fill out the corresponding box for each question. Please note that all NEI SBIR/STTR grantees funded at the time of application are eligible to apply for this program. All applicants will be notified as to whether or not their application has been accepted to the program. Selected participants will be assigned a regulatory consultant with the appropriate expertise to create a customized regulatory approval strategy.

**Applications will be accepted and reviewed on an ongoing basis until March 5, 2012 5:00 p.m. EST. Final selection of participants will be made by April 2, 2012.**

Potential applicants are strongly advised to contact Dr. Jerome Wujek ([wujekjer@nei.nih.gov](mailto:wujekjer@nei.nih.gov); 301-451-2020) before beginning application process.

## **Application Requirements:**

- The program is open to all active NEI Phase I and II grantees.
- Only one application per company will be accepted.
- Participants will be selected based on regulatory need, maturity of the product/technology, and its potential impact on treatment or diagnosis of visual diseases or disorders.

**Company Name:**

**Address:**

**Website (if any):**

**Project Title:**

**SBIR/STTR Project Number:**

**Date of Submission of Application:**

**Principal Investigator Name:**

**Phone(s):**

**Email:**

## **Nature of Product:**

### **A. Therapeutic:**

Please provide a one to two page project summary that addresses the innovations of the product under development, its advantages over the current state-of-the-art, its indication(s) and how it will improve eye care. This summary should include the following:

- Active ingredient
- Formulation
- Primary therapeutic indication or intended patient population
- Stage of development (e.g. optimized lead, formulation, design freeze, etc.) and whether the manufacturing process is known and/or scalable
- One paragraph summary of in vitro results
- One paragraph summary of in vivo animal results, if any
- One paragraph summary of human clinical results, if any

**OR**

### **B. Medical Device:**

Please provide a one to two page project summary that addresses the innovations of the product under development, its advantages over the current state-of-the-art, its indication(s) and how it will improve eye care. This summary should include the following:

- Device purpose
- Device description and drawings (if appropriate and available)
- Primary therapeutic indication or intended patient population
- Stage of development (e.g. prototype, design freeze, etc.) and whether the manufacturing process is known and/or scalable
- One paragraph summary of bench test results
- One paragraph summary of in vivo animal results, if any
- One paragraph summary of human clinical results, if any

Provide a one page discussion of why the product/technology may require FDA approval.

Using no more than half a page, list any specific questions that you have regarding the regulatory process pertaining to your project.

Email application form to Jerome R. Wujek, Ph.D. at [wujekjer@nei.nih.gov](mailto:wujekjer@nei.nih.gov)  
or fax to 301-496-2297.