

# Eye Product Assistance Center (EPAC) Request Form

The Eye Product Assistance Center (EPAC) is an in-kind consulting service provided by the National Eye Institute (NEI). It is available to all investigators developing regulated products for diseases or disorders of the visual system.

## Eligibility and Selection

- Investigators do not need active NEI or NIH funding to request support.
- Alignment with the NEI mission and a disease or disorder of the visual system.
- Clear intent to develop a regulated medical product for a specific indication or intended use.
- Level of need, including whether comparable support is already available through an active award, supplement, contract, vendor, or institutional resource.
- Likelihood that no more than 20 hours of consulting can produce a useful, actionable deliverable.
- Order of submission may be used as a tiebreaker after programmatic and readiness criteria are assessed

## Scope of Support

The EPAC consults on product development at any stage, from proof-of-concept to clinical trials, provided the effort is intended for a regulated medical product with a specific indication. Consultant support is available for activities such as:

- Needs assessment
- Device design, and prototyping
- Chemistry, Manufacturing, and Controls (CMC)
- Assay development and Biostatistics
- Pharmacokinetics/Pharmacodynamics (PK/PD) and ADME
- Toxicology and Quality Assurance/Quality Control (QA/QC)
- Regulatory affairs and operations
- Medical writing and first-in-human trial planning

## Important Disclaimers

- **Responsibility:** Investigators remain fully responsible for their product development efforts; the EPAC provides recommendations only.
- **No Programmatic Advantage:** Utilizing the EPAC or following its recommendations does not provide an advantage for future proposals submitted in response to NEI/NIH NOFOs.
- **Not a Substitute:** The EPAC should not be utilized in place of activities that could be supported by individual investigator's active product development grants or appropriate supplemental opportunities.
- **Exclusions:** The EPAC does not provide grant writing or editing support.
- **Confidentiality/data handling:** Project information may be reviewed by NEI staff and, if approved, by screened consultants needed for the requested expertise.
- **Other Support:** EPAC consultant time and services should be identified in Other Support for all Federal grant applications.

## **Investigator Information**

**Lead Investigator Name:**

**Title/Position:**

**Institution/Organization:**

**Organization Type (academic, business, nonprofit):**

**Email Address:**

**Phone:**

## **Current Funding and Resources**

- Active NIH/NEI support? yes/no; award number(s):
  
- Other active product-development support? foundation, industry, institution, contract, vendor:
  
- Pending Applications or Supplements? yes/no; identify mechanism if known:
  
- Why EPAC support is needed? explain why the gap is not covered by existing resources:

## **Product Development Details**

### **1. Long-Term Goal- Product Profile and Regulatory Development Plan**

*Describe the product, specific indication, product type (e.g., diagnostic, therapeutic, biologic, small molecule, device, combination), regulatory pathway, current maturity, and projected timeline.*

## **2. Short-Term Goal (< 5 Years)**

*Identify the major milestones expected within five years, including regulatory submissions/interactions, manufacturing or quality-system milestones, nonclinical studies, assay/device validation, and first human-use or clinical milestones.*

### **3. Requested Consultant Support & Justification**

*Detail each activity separately, list activities in order of priority, and provide a brief justification. Total consultant support is limited to 20 hours per calendar year.*

**Acknowledgments**

EPAC provides recommendations only; the investigator remains responsible for product-development decisions.

EPAC use does not confer advantage in NEI/NIH funding decisions.

I am not requesting grant writing, grant editing, or proposal strategy support.

The requested work is not already covered by an active product-development award, supplement, contract, vendor, or institutional resource; or I have explained the gap.

Project information may be reviewed by NEI staff and, if approved, by screened consultants as needed for the requested expertise.

**Authorized Organization Representative (AOR) Acknowledgement of EPAC Request**

**Name:**

**Signature:**

**Date:**

Please send completed forms to [NEI\\_extramural@nih.gov](mailto:NEI_extramural@nih.gov). Please include EPAC request, PI's name, and date in the subject line.

For question concerning the EPAC please contact [tony.gover@nih.gov](mailto:tony.gover@nih.gov).