How to Apply for a Grant

U.S.-India Collaborative Vision Research
NEI Grant Writing Workshop

September 13, 2019

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National Eye Institute

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“Outline”

- NIH Institutes & Centers
- How to Find Funding?
- How to Apply?
- Center for Scientific Review
- Criterion Scores
- Early Stage Investigators
- National Advisory Eye Council
- NIH RePORTER and Mobil App
We are NIH

Learn about our mission, our people, the patients who partner with us, and what drives us to improve health and fight disease.

Learn more »

www.nih.gov
Office of Extramural Research (OER)

Find Funding

How to Apply

Explore NIH Funded Research (RePORT)

Grants Process Overview

Get Started

Learn the Basics
Understanding NIH
What Does NIH Look For
Who is Eligible
Types of Grant Programs
Types of Applications
Plan Your Application

Application Referral and Review

Receipt and Referral
Peer Review
Pre-Award and Post-Award Processes
Pre-Award and Award Process
Post Award Monitoring and Reporting
Forms Library

How to Apply

Prepare to Apply
Systems and Roles
Register
Understand Funding Opportunities
Types of Applications
Submission Options
Obtain Software

Write Application
Write Your Application
Develop Your Budget
Format Attachments
Page Limits
Data Tables
Reference Letters
Biosketches

Submit
Submit, Track, and View
How We Check for Completeness
Changed/Corrected Applications

Application Form Instructions
How to Apply Video Tutorials

https://grants.nih.gov/grants/oer.htm
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How to Find Funding?
Grants.NIH.gov (Grants.gov)

2 Functions

- **Find Funding Opportunities**
  - List active Funding Opportunity Announcement (FOA) and Notices.
    
    https://grants.nih.gov/funding/searchguide/index.html#

  - Includes all FOAs from all federal/government agencies including DOD, FDA, CDC, USDA.

- **Apply**
  - The site where you apply for your grant, i.e., submit your application.
  - Electronic application submission
# Search for U.S.-Indo Program Announcement (Funding - NIH Guide to Grants and Contracts)

## Active Program Announcements (PAs)

Search Term(s): NEI, PAR-18-912

### Matching Records: 1

<table>
<thead>
<tr>
<th>Announcement Number</th>
<th>Related Announc.</th>
<th>Issuing Organization</th>
<th>Release Date *</th>
<th>Opening Date (SF424 Only)</th>
<th>Expiration Date</th>
<th>Activity Code(s)</th>
<th>Title</th>
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<tbody>
<tr>
<td>PAR-18-912</td>
<td>See Related</td>
<td>NEI</td>
<td>09/07/2018</td>
<td>10/08/2018</td>
<td>11/10/2020</td>
<td>R01</td>
<td>U.S. - India Collaborative Vision Research Program (R01 Clinical Trial Not Allowed)</td>
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</table>

[https://grants.nih.gov/grants/guide/search_results.htm?scope=pa&year=active](https://grants.nih.gov/grants/guide/search_results.htm?scope=pa&year=active)
Part 1. Overview Information

<table>
<thead>
<tr>
<th>Participating Organization(s)</th>
<th>National Institutes of Health (NIH)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components of Participating Organizations</td>
<td>National Eye Institute (NEI)</td>
</tr>
<tr>
<td>Funding Opportunity Title</td>
<td>U.S. - India Collaborative Vision Research Program (R01 Clinical Trial Not Allowed)</td>
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<tr>
<td>Activity Code</td>
<td>R01 Research Project Grant</td>
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<td>Announcement Type</td>
<td>Reissue of PAR-15-320</td>
</tr>
<tr>
<td>Funding Opportunity Announcement (FOA) Number</td>
<td>PAR-18-912</td>
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<tr>
<td>Companion Funding Opportunity</td>
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<tr>
<td>Number of Applications</td>
<td>See Section III. 3. Additional Information on Eligibility.</td>
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<tr>
<td>Catalog of Federal Domestic Assistance (CFDA) Number(s)</td>
<td>93.857</td>
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</table>

This Funding Opportunity Announcement (FOA) encourages Multiple Principal Investigator (Multi-PD/F01) applications from United States (U.S.)-based institutions with an Indian institution partner to establish bilateral collaborations that will advance science and technology important to understanding, preventing, and treating blinding eye diseases, visual disorders, and their complications.

Applications are encouraged from organizations/institutions that propose to conduct research on the basic biology and/or genetics of ophthalmic diseases through collaborations with Indian investigators on the following: diabetic retinopathy, glaucoma, age-related macular degeneration, retinitis pigmentosa, including rare and genetic diseases such as congenital cataracts, as well as other eye conditions such as uveal inflammation/uveitis, refractive error, low vision, and corneal injury. Basic, translational, or epidemiological research may be proposed. Clinical trials will not be supported under this FOA.

Purpose:
- establish bilateral collaborations with U.S.-based institutions and Indian-based institutions

Research focus:
- basic biology and/or genetics of ophthalmic diseases

Areas include:
- diabetic retinopathy, glaucoma, age-related macular degeneration, retinitis pigmentosa,
- rare and genetic diseases such as congenital cataracts
- eye conditions such as ocular inflammation/uveitis, refractive error, low vision, and corneal injury.

Collaborations

The FOA requires that the collaboration between the U.S. and Indian research teams be submitted as a Multiple Principle Investigator (Multi-PD/PI) application with both of the lead scientists from each country as the PD/PI. Applications may be derived from existing collaborations with an established history of interaction, or from new partnerships developed in response to this FOA. The collaboration must be based on interactive relationships that maximize the expertise of the individual U.S. and Indian research teams.

Through this FOA, U.S. and Indian collaborating investigators should work together to develop and submit an application to National Institutes of Health (NIH) and the India Ministry of Science and Technology's Department of
U.S. - India Collaboration

Research Project Grant Applications

- Mechanism: R01 Basic Research, Investigator Initiated
- Multiple Principle Investigator (Multi-PD/PI) application with both of the lead scientists from each country as the PD/PI.
- Budgets are limited to $250,000 annual direct cost.
- Award project period is limited to 3 years.
- No clinical trials
- No revisions
# U.S.-Indo Application Due Dates

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<tr>
<th></th>
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<tbody>
<tr>
<td>Earliest Start Dates</td>
<td>July 2019</td>
<td>July 2020</td>
<td>July 2020</td>
</tr>
</tbody>
</table>

Adapted from: [https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm#review](https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm#review)
“Outline”

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How to Apply to PAR-18-912

Note: Organizations must register and apply with their eRA Commons. All U.S. and Indian applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration.
Applying for a grant requires 2 Separate Systems Working Together

**Grants.gov** – required to prepare and submit grant applications

- The site where you apply for your grant, i.e., submit your application.
- Submission of your application must be electronically.

**eRA Commons** – required to do business with NIH

- Organizations must register and apply with their eRA Commons.
- Allows you to track your application.
- Allows you to view the same image of your application that NIH staff and reviewers see.
- Online interface where you go to access grant information such as Institute/Center assignments, review outcomes, summary statements, and Notices of Awards.
Organization Registration

Your organization must be registered in multiple systems to submit. Start early – can take 6 weeks!

**DUNS number** (Data Universal Numbering System) – provides unique organization identifier
- Need DUNS number in order to apply for a grant in Grants.gov
- All U.S. and Indian applicants must have an active DUNS number.

**SAM registration** (System for Award Management): – needed to do business with government
- Need SAM registration in order to complete the eRA Commons registration
- Non-U.S. organization: Need NCAGE code prior to registering with SAM.
- Requires annual renewal

**Grants.gov** – required to prepare and submit your application

**eRA Commons** – required to do business with NIH

How to Access Grant Application Forms:

- There is no universal form set available for download.
- Each FOA guides you to the systems
- 3 online program, ASSIST, Workspace, system-to-system solution, through which you can download application forms and submit your application.
- Active Grants.gov and eRA Commons credentials and are required to prepare and submit an application using these 3 programs.
- For foreign entities, SAM registration is also required in order to submit an application

Example – Assist
(Application Submission System & Interface for Submission Tracking)

Required Application Instructions
It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise (in this FOA or in a Notice from NIH Guide for Grants and Contracts).

Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Applications that do not comply with these instructions may be delayed or not accepted for review.

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You must use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov Workspace to prepare and submit your application and eRA Commons to track your application.

- Application Guide
- Assist User Guide
“Outline”

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An NIH Grant Application Goes Through Two Levels of Review

- **Center for Scientific Review**
  Assigned to a Scientific Review Group (SRG)
  Often referred to as the “Study Section” for Peer Review

- **National Advisory Eye Council (NAEC)**
  Second Level of Review
Review of NIH Grant Mechanisms and Study Section Assignment

All applications Received electronically through grants.gov

Center for Scientific Review (CSR)

Division of Receipt & Referral

www.CSR.NIH.Gov

1R01EY012345-01

Funding Institute

Study Section for Review
CSR Study Sections: NEI U.S.-Indo Applications

Vision-centric study sections:
BVS: Biology of the Visual System
DPVS: Diseases and Pathophysiology of the Visual System

Other study sections:
BCHI: Biomedical Computing and Health Informatics
DDR: Drug Discovery and Mechanisms of Antimicrobial Resistance
GCAT: Genomics, Computational Biology and Technology Study Section
GDD: Gene and Drug Delivery Systems Study Section
GHD: Genetics of Health and Disease Study Section
KNOD: Kidney, Nutrition, Obesity and Diabetes Study Section
NOIT: Neuroscience and Ophthalmic Imaging Technologies Study Section
ZRG1 BDCN-J: Center for Scientific Review Special Emphasis Panel
   Ocular Surface, Cornea, Anterior Segment Glaucoma and Refractive Error
First Level of Review
Center for Scientific Review (CSR)

- Each scientific review group (SRG) is led by a scientific review officer (SRO) – that organizes the review meeting, recruits qualified reviewers; identifies conflicts, and assigns applications, and prepares summary statements.

- Chair – moderates the discussion as well as serves as a reviewer.

- Each FOA specifies all of the review criteria and considerations to be used to evaluate applications.

www.CSR.NIH.Gov
Scored Review Criteria (5)

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment
Section V.

Application Review Information

Scoring Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

**Significance**

- Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

- Is the proposed project likely to stimulate collaborative basic, translational, or applied research between U.S.-based researchers and Indian researchers?

**Approach**

- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

- Does the application provide appropriate plans for the collaborative research, demonstrating the integration of the U.S. and Indian collaborator efforts, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts? Does the application provide appropriate contingency plans and/or solutions for addressing setbacks and delays?

- If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed?

**Environment**

- Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the proposed project? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

- Is the collaboration plan well-defined with clearly identified responsibilities for the U.S. and Indian collaborators, and does it take advantage of the strengths of each collaborator?
Additional Review Criteria & Considerations

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and will provide an overall impact score, but will not give separate scores for these items.

**Protocols for Human Subjects**

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects.

**Inclusion of Women, Minorities, and Children**

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex, gender identity, race, and/or ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research.

**Vertebrate Animals**

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia methods if not consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section.

**Biohazards**

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

**Resubmissions**

Not Applicable

**Renewals**

Not Applicable

**Revisions**

Not Applicable

**Additional Review Considerations**

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

**Applications from Foreign Organizations**

Not Applicable

**Select Agent Research**

Reviewers will assess the information provided in this section of the application, including: 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

**Resource Sharing Plans**

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) Data Sharing Plan; (2) Sharing Model Organisms; and (3) Genomic Data Sharing Plan (GDS).

**Authentication of Key Biological and/or Chemical Resources**

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

**Budget and Period of Support**

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.
<table>
<thead>
<tr>
<th>Overall Impact or Criterion Strength</th>
<th>Score</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>1</td>
<td>Exceptional</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
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<tr>
<td>Medium</td>
<td>4</td>
<td>Very Good</td>
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<td></td>
<td>5</td>
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<td>Fair</td>
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<td></td>
<td>8</td>
<td>Marginal</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
</tr>
</tbody>
</table>
Scoring Overall Impact of R or U mechanisms

Overall Impact:
The likelihood for a project to exert a sustained, powerful influence on research field(s) involved

Evaluating Overall Impact:
Consider the 5 criteria: significance, investigator, innovation, approach, environment (weighted based on reviewer's judgment) and other score influences, e.g. human subjects, animal welfare, inclusion plans, and biohazards

- High Impact:
  - Score: 1, 2, 3
  - e.g. Applications are addressing a problem of high importance/interest in the field. May have some or no weaknesses.

- Medium Impact:
  - Score: 4, 5, 6
  - e.g. Applications may be addressing a problem of high importance in the field, but weaknesses in the criteria bring down the overall impact to medium.
  - e.g. Applications may be addressing a problem of moderate importance in the field, with some or no weaknesses.

- Low Impact:
  - Score: 7, 8, 9
  - e.g. Applications may be addressing a problem of moderate/high importance in the field, but weaknesses in the criteria bring down the overall impact to low.
  - e.g. Applications may be addressing a problem of low or no importance in the field, with some or no weaknesses.

5 is a good medium-impact application, and the entire scale (1-9) should always be considered.
Sample Summary Statement of an Application that was Discussed and Scored

New Indicator for ESI status

Percentile from 1-100 in whole numbers

Impact/Priority Score in 10-90 range (avg x 10)

• Rank order based on scores from current + 2 previous study sections
• Normalizes scores between study sections
• NOT an award rate!

NEI Program Officer
Contact info

John Smith MD
1 R01 EY123456-01
Sample Summary Statement of an Application that was Not Discussed (ND)

Explanatory paragraph

**NOTE TO APPLICANT:** As part of the initial scientific merit review process, reviewers were asked to identify those applications with the highest scientific merit, generally the top half of applications that they customarily review. At the study section meeting, those applications were discussed and assigned a priority score. All other applications, including this application, did not receive a score. Provided is a compilation of reviewers' comments prepared prior to the meeting, without significant modification or editing by NIH staff.

**EARLY STAGE INVESTIGATOR**

**NEW INVESTIGATOR**

No Impact/Priority Score

Foot Note starts with ++
Structured Critiques

Criterion Scores appear at beginning of each critique

Structured Critiques
Review criteria comments in bullet format

Overall Impact comments in paragraph format

Criterion Scores are independent of the Overall Impact Score

CRITIQUE 1:

Significance: 1
Investigator: 2
Innovation: 2
Approach: 2
Environment: 1

Overall Impact:
The work proposed in this grant application will have high potential impact in the clinically important area of safe blood transfusion. The investigators are highly qualified with complementary expertise. This will help ensure success of the work. There is also novel application of incident reporting methods now in use in other fields, which could lead to improved public confidence in the blood supply. The study will bring a rigorous, systematic approach to the current reporting process, which is empiric and lacking in evaluation. The weaknesses of the application include a lack of representation of non-academic transfusion medicine practitioners, which may make incident reporting less effective in non-academic hospital settings. There is not enough time allotted for aim one work, and aims two and three are somewhat dependent on the success of aim one.

1. Significance
Strengths
• An effective incident reporting system
• Models developed for other error-critical fields have been effectively adapted in the development of an incident-reporting system for transfusion medicine.
• Identifies and incorporates limited and appropriate range of human error patterns—will be easily transferable to practice.
• Could be generally applicable to understanding influence of incentives—deincentives on behavior.

Weaknesses
• Lack of representation of non-academic transfusion medicine practitioners, which may make incident reporting less effective in non-academic hospital settings.
• Unclear how incident reporting system would be utilized to reduce human error.
• Unclear whether public perception or clinical need is target of model application.

2. Investigators
Strengths
NIH Institutes & Centers

How to Find Funding?

How to Apply?

Center for Scientific Review

Criterion Scores

Early Stage Investigators

National Advisory Eye Council

NIH RePORTER and Mobil App
Designate Investigator Status
Sample Summary Statement

**NOTE TO APPLICANT:** As part of the initial scientific merit review process, reviewers were asked to identify those applications with the highest scientific merit, generally the top half of applications that they customarily review. At the study section meeting, those applications were discussed and assigned a priority score. All other applications, including this application, did not receive a score. Provided is a compilation of reviewers’ comments prepared prior to the meeting, without significant modification or editing by NIH staff.
Early Stage and Early Established Investigators

- **Early Stage Investigator (ESI)** - a PI who has completed his or her terminal research degree or medical residency—whichever date is later—within the past 10 years and has not yet competed successfully for a substantial, competing NIH research grant.

- **Early Established Investigator (EEI)** - a PI within 10 years of receiving their first substantial, independent competing NIH R01 equivalent research award as an ESI.

**Need** to keep your eRA Commons profile up-to-date.

Benefits of Being a ESI or EEI

Peer review:

- Special considerations regarding publication record and preliminary data
- Focus more on approach than on their track record.
- Summary statements are usually released more quickly.

Differential pay plan:

- Usually treated more generously on funding.
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National Advisory Eye Council (NAEC)

Second Level of Review

Not a second scientific review

The NAEC advise, assist, and consult with, to make recommendations to the NEI Director on matters related to funding activities and policies decisions.

- Determines programmatic relevance to the mission of the NEI.
- Sets the goals and research priorities of each NEI program.
- Discuss all concepts, workshops, and FOA's in general.
- Looks at applications with potential barriers to funding such as human subjects and animal concerns, or special circumstances such as foreign applications and renewal applications requesting more money than the limit.
NIH Institutes & Centers

How to Find Funding?

How to Apply?

Center for Scientific Review

Criterion Scores

Early Stage Investigators

National Advisory Eye Council

NIH RePORTER and Mobil App
RePORTER

- Enables investigators to search a repository of NIH funded research project grants & access publications and patents resulting from NIH funding as well as find the Program Officer in the field

https://projectreporter.nih.gov/reporter.cfm
NIH RePORTER
Research Portfolio Online Reporting Tools

https://projectreporter.nih.gov/reporter.cfm
NIH RePORTER Search Results
(PAR-15-320)

- Principal Investigator
- Title
- Abstract Text
- Public Health Relevance Statement

https://projectreporter.nih.gov/reporter.cfm
Convenience Comes to Federal Grants

Download the Grants.gov Mobile App To search and submit on the go.

Download on the App Store | GET IT ON Google Play
Questions?