

NIH Venture Program Oculomics Initiative Research Opportunity Announcement OTA-24-006:

*Development and Application of
Ophthalmic Imaging Technologies
to Advance Our Understanding of
Systemic Diseases*

4 April 2024

Oculomics Initiative Working Group



National Institutes of Health
Office of Strategic Coordination – The Common Fund

Agenda

- Overview of the new Common Fund Venture Program
- Overview of the Oculomics Initiative Research Opportunity Announcement (ROA)
- Questions & Answers

Overview of the new Common Fund Venture Program

Common Fund Venture Program

“Amazing things with modest funding”

The Venture Program will make Common Fund support available for short-term initiatives that embrace scientific risk

Prioritized by ICO Director Venture Board, with final approval by NIH Director

Criteria:

- Emphasis on **innovation** and **speed**
- Projects should have **potential for major impact** and **embrace scientific risk**

Features of Venture Space projects:

- Brief funding, no more than **3 years**
- Clearly defined goals with **go/no-go milestones**
- **Flexible approach** to funding mechanisms and project timelines
- **Smaller scale** cross-cutting initiatives
- **Nimble, streamlined** management

Overview of the Oculomics Initiative

New Venture Initiative: Oculomics Initiative

Background and Goals:

Ocular imaging technologies provide direct, in vivo measurements of biomarkers for a wide variety of diseases and conditions, including neurodegenerative, metabolic, renal, inflammatory, and cardiovascular diseases.

Issues limiting clinical utility: 1) non-disease specific biomarkers 2) lack of specificity and sensitivity

New imaging technologies provide

- 1) superior resolution and image depth compared to classical OCT and fundus imaging.
- 2) functional measurements: electrical activity, blood flow, redox state, and metabolic rates of oxygen.
- 3) substance identification including, water, protein, lipid, and collagen/elastin content.

Imaging Tech + Machine Learning => Clinically useful biomarker identification for a range of diseases

This Venture initiative would support development and application of novel, and noninvasive ocular imaging technologies and tools to identify systemic disease biomarkers with high sensitivity and specificity.

New Venture Initiative: Oculomics Initiative

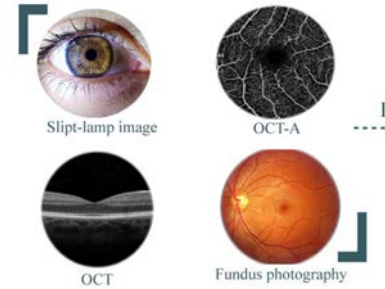
Anticipated Work Products:

- Development and application of non-invasive imaging technologies and AI/ML algorithms for identification of novel & clinically relevant biomarkers.
- By the end of the three-year period of performance, developed technologies should be demonstrated in appropriate animal models of disease or human patients.

Impact:

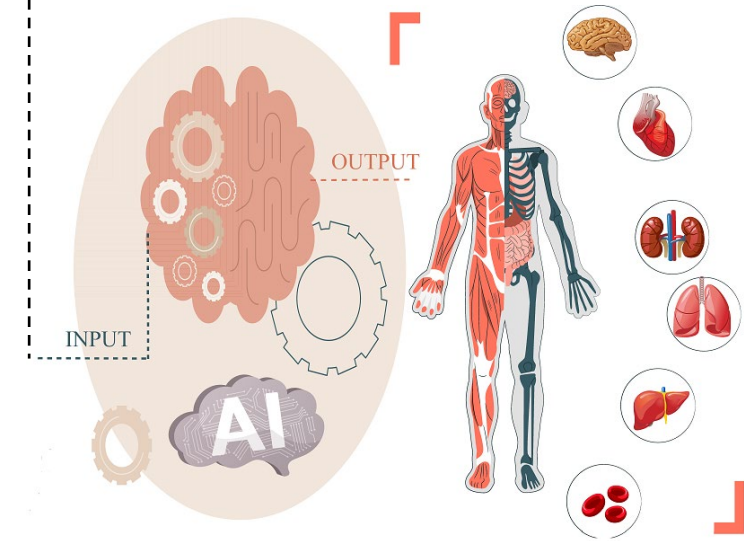
- Improved screening, diagnosis, and monitoring of a wide range of diseases using ocular biomarkers.
- Enabling new discoveries at scale: widespread use in research and clinical settings.

Classical Imaging Technologies



Example New Imaging Technologies

- adaptive optics OCT (AO-OCT)
- AO two-photon microscopy
- scanning Laser Ophthalmoscope
- spectral Domain-OCT
- super-resolution ultrasound localization microscopy
- visible-light OCT
- opto-acoustic techniques
- terahertz imaging
- retinal hyperspectral imaging



Modified Image from: Li, H.; Cao, J.; Grzybowski, A.; Jin, K.; Lou, L.; Ye, J. Diagnosing Systemic Disorders with AI Algorithms Based on Ocular Images. Healthcare 2023, 11, 1739.

Other Transactions

- **Not a grant, cooperative agreement, or a contract**
- OTs allow the **nimble addition or subtraction** of expertise, tools, technologies, and partnerships
- Many Public Policies apply to OT, though not FAR or NIH Grants Policy
- Objective Review of OTs **do not follow traditional NIH review process**. The OT Team develops the criteria and composition of the review which is designed to ensure integrity, fairness and transparency.
- Award **funding is different** (e.g., variable segment lengths, no future commitment, can be terminated or extended by NIH, etc.)
- Changes in project and budget are different (e.g., **NIH can propose changes**, threshold for prior approval, etc.)

OTA-24-006

<https://commonfund.nih.gov/venture/oculomics>

The purpose of this ROA is to support the development and application of noninvasive ophthalmic imaging technologies to advance our understanding of systemic diseases.

- The anticipated outcome of proposed efforts will be the development, application and initial demonstration of new imaging technologies and machine learning algorithms for the detection and identification of novel systemic disease biomarkers.
- ROA strongly encourages applicants to form multidisciplinary teams that consist of academic/industry experts relevant to the research plan (i.e., device developers, imaging bioengineers, vision scientist and clinicians, and biomedical scientist and clinicians with expertise in specific systemic disease areas).
- ROA is not intended to support expansion of previous or ongoing efforts that currently utilize OCT, OCTA or fundus photography for detection of systemic diseases.

Plan for Enhancing Diverse Perspectives (PEDP)

The application must include a Plan for Enhancing Diverse Perspectives (PEDP). Diverse perspectives can refer to people who do the research and the places where the research is done, as well as to who participates in the research as a part of the study population. Must include:

- Description of defined activities and actionable strategies for the inclusion of diverse perspectives in the project.
- Description of how the PEDP will bring advantages or unique capabilities to the project.
- Milestones for the evaluation of PEDP activity progress and success.
- Anticipated timeline of proposed PEDP activities.

Please note – the PEDP is a part of the criteria that will be scored during the Objective Review

Data Sharing and Management

- All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.
 - Notice Number: NOT-OD-23-053
- Must develop and maintain good documentation and manuals/training materials.
- Scientific data should be made accessible as soon as possible, and no later than the time of an associated publication or the end of the performance period of the extramural award that generated the data.

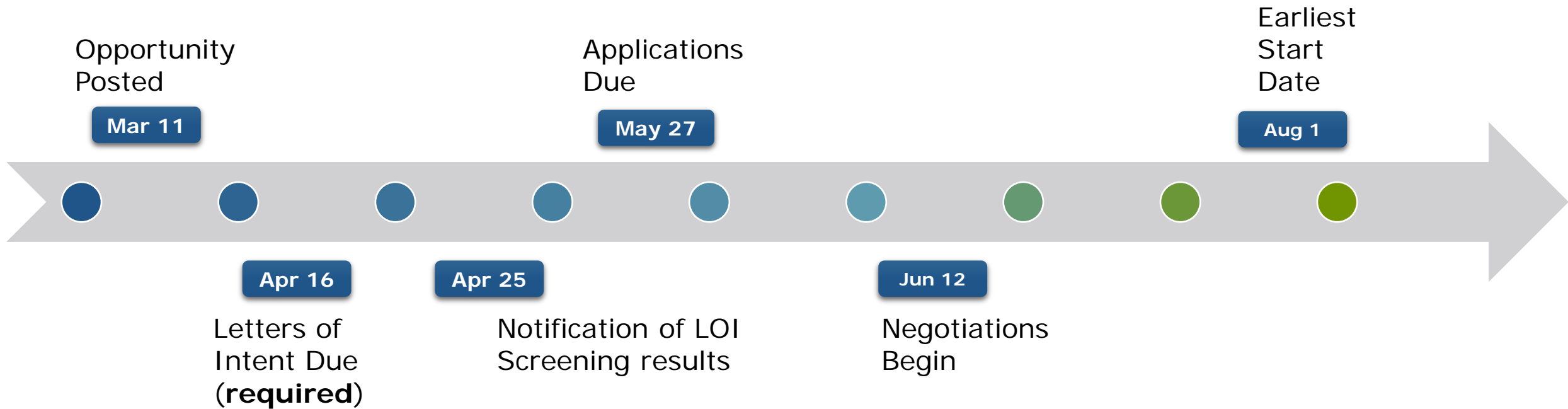
PI Eligibility and Minimum Effort Requirements

- More than one individual may be named as PI; one individual must be identified as the contact PI.
- The contact PI must be employed by or affiliated with the applicant organization.
- If a multiple Principal Investigator (MPI) application is submitted, an MPI leadership plan is required as part of the overall Leadership Plan.
- PI must commit at least 10% level of effort to the project.

Letter of Intent (LOI)

- LOIs are **required** to be eligible to submit a full proposal. **Only invited applicants meeting LOI screening criteria will be eligible to submit a full application.**
- Letters of intent must be submitted by email to oculomics@od.nih.gov.
- Due Date: **16 April 2024**
- LOI requirements and screening criteria are outlined in the ROA.
- NIH will **not** provide feedback about the scientific and technical content of the LOI, **nor** make recommendations for improvements.
- Notification of LOI Screening results will be provided to applicants by **25 April 2024**.

Timeline Overview



Due date: 27 May 2024

- Applications will have multiple components as listed in the ROA
- If applicable, page limits for components are stated in the ROA
- Title the components the same way they are named in the ROA
- **Due by 5 pm local time of applicant organization. Late applications will not be accepted**
- Applications must be submitted electronically through ASSIST.

For additional information:

Visit the FAQ page: <https://commonfund.nih.gov/venture/oculomics/faqs>

Contact the Program Team: oculomics@od.nih.gov



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Questions and Answers

Thanks for attending



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