PREVENT BLINDNESS
POLICIES & PROCEDURES

Policy Name:	Research Policy
Approved by Committee:	
Approved by Board:	Approved by Board of Directors, June 1997 Amended by the Board of Directors, July 2004 Amended by the Board of Directors, July 2021

Prevent Blindness is committed to promoting and sponsoring vision and eye health research.

I. Extramural Research

Extramural research refers to research sponsored by Prevent Blindness and/or its affiliates but in which Prevent Blindness and/or its affiliates has no direct participation.

Prevent Blindness administers a public health research program – The Prevent Blindness Joanne Angle Investigator Awards (*This is* not *an annual award, as it operates only in years in which funding is available and budgeted*.)

Prevent Blindness Joanne Angle Investigator Award

A. Purpose

The Prevent Blindness Joanne Angle Investigator Award provides funding for clinically-based research investigating public health issues related to the burden of illness of eye-related health and safety topics. All research grants must focus on preserving sight and preventing blindness.

Funding priority is given to projects for research relating to clinically important eye diseases. Prevent Blindness will give preference to clinical and disease-oriented grants or grants which investigate public health issues related to the burden of illness of eye-related health and safety topics. All research grants need to promote the core mission of Prevent Blindness – preventing blindness and preserving sight. Basic laboratory science research will not be supported under this program. However, topical areas of interest for this program could include, but are not limited to:

1. research into the causes and potential prevention of ocular disease and vision loss on a population basis;
2. the development and evaluation of new early detection technologies and strategies;
3. evaluation of interventions designed to prevent or delay the onset of ocular diseases;

4. evaluation of new approaches to screening including testing strategies, outreach to high-risk populations, follow-up protocols, and issues of patient compliance with screening recommendations;
5. development and evaluation of interventions to improve compliance with chronic medical therapy for glaucoma and other disorders requiring long-term treatment;
6. health services research designed to evaluate new strategies for delivery of eye care services, especially to underserved populations; and
7. studies to document the burden of ocular disease and vision loss, and their consequences to the population.

The research program accountability is assigned to the Public Health and Policy Committee who has the authority to delegate review responsibility to another committee, if appropriate, and with consultation of the CEO and Board Chair.

B. Grants

Grants fund studies of priority interest for investigators who need assistance to defray costs of personnel, equipment and consumable supplies as needed for a specific research investigation. Travel costs are generally not supported but may be considered. Grants are typically awarded for a one-year period.

C. Renewals

Renewal support may be provided where funding is available and significant research results have been obtained. Award recipients interested in renewal support must submit a progress report along with the standard renewal application.

D. Policies and Procedures

In years in which the Award is funded, detailed policies and procedures, including timeline, will be made available on the Prevent Blindness website. All materials submitted through the application process are the property of Prevent Blindness and cannot be returned to the investigator.

E. Notification and Acceptance

Upon notification of an Award, a signed letter of acceptance must be returned to Prevent Blindness prior to project initialization. Included with the letter of acceptance, award recipients are required to submit a lay description of their research project. Due to limited resources for program administration, critiques of applications are not available.

F. Payment

Equal quarterly payments will be made to the investigator's institution unless other arrangements are negotiated in advance. No institution overhead charges are funded by Prevent Blindness. An annual report and a project completion report will be required.

G. Final Report

A project report on the work conducted must be submitted within 60 days of the conclusion of the grant period. Manuscripts are acceptable in lieu of a final report. Also, a brief lay description of results and potential impact for eye disorders or research is required. A final expenditure report and refund of any unused portion of the award is required with the project report.

H. Manuscripts and Acknowledgements

All manuscripts, abstracts, reports and other publications resulting from Prevent Blindness's support must acknowledge that the study was funded (in whole or in part) by a grant from Prevent Blindness. If awards are funded through a specific source, the investigator will be advised as to the appropriate acknowledgement. Manuscripts should be forwarded to Prevent Blindness, upon acceptance, with the name of the journal in which it will be printed.

I. Extensions and Budget Changes

Time extensions to complete a project are allowed if the investigator cannot provide an adequate report within the allotted time. Commencement dates may be delayed if extenuating circumstances prevent a study from going forward. A written request is required for no-cost time extensions and should include the reason for delay, additional time required, summary of work accomplished to date, and a report indicating expenditures and any unexpended balance. Rebudgeting is encouraged if required to accomplish the goals of the project. A written request and Prevent Blindness approval are required to rebudget personnel and equipment categories.

J. Termination

If circumstances prevent completion of the grant, Prevent Blindness must be notified immediately. A report on the work conducted to the date of termination is required. Any unused portion of the grant must be returned with a final expenditure report.

K. Investigator Qualifications

While investigators may reside out of the U.S., all sponsoring organizations (those through which funding flows) must be based in the United States or Canada. Additionally, the funded project must have outcomes that will have direct application to vision and eye health in the U.S. that support the mission of Prevent Blindness. All published materials and positions relative to research and eye-health will be listed on the application. Level of experience and related fieldwork will be taken into consideration by the reviewers. A complete budget and detailed description of the research project will be required.

L. Support from Other Sources

Any source of funding that has already been secured must be declared to Prevent Blindness upon submission of the application. A list of all monies received and promised for the project must be listed on the application along with conflict of interest disclosures.

Extramural Research Partnerships

Prevent Blindness and its affiliates may partner with other organizations on extramural research which supports the mission of Prevent Blindness.

For example, currently (as of 2020), Prevent Blindness co-funds a yearly joint public health research program with Fight for Sight (FFS) – the Fight for Sight-Prevent Blindness Joanne Angle Public Health Award (not to be confused with the "Prevent Blindness Joanne Angle Investigator Award," previously discussed) – to serve the missions of both organizations. Selection criteria is established by the FFS Scientific Review Committee, to which Prevent Blindness may assign a reviewer for purposed of this grant. FFS, with input from Prevent Blindness, utilizes the terms, guidelines, review processes and funding mechanisms of its current grant structures.

II. Intramural Research

Intramural research refers to research conducted, in whole or in part, by or on behalf of Prevent Blindness or its affiliates (e.g., Vision Problems in the U.S., Future of Vision, Cost of Vision Problems reports).

Intramural Research Review and Approval Procedures

A. Purpose

Review and approval of all Prevent Blindness intramural research activities (whether driven by Prevent Blindness or an affiliate) is intended to ensure the scientific validity and appropriateness of studies involving Prevent Blindness in any way. Failure to maintain the highest standards of scientific credibility could seriously damage the reputation of Prevent Blindness. The Prevent Blindness Public Health and Policy Committee has the authority to delegate review responsibility to another committee, if appropriate, and with consultation of the CEO and Board Chair.

B. Protocol Submission

At least eight weeks prior to commencement of any research activity, a complete study protocol must be submitted on an **Intramural Research Protocol Submission Form** (included at the end of this Policy Statement) to the Prevent Blindness Public Health and Policy Committee

The protocol must designate a principal investigator with appropriate credentials who is directly responsible for the execution of the study. A copy of the principal investigator's curriculum vitae must be attached to the protocol.

All research proposals should be assessed for the need of Institutional Review Board (IRB) approval. If it is needed, the applicant and/or principal investigator should secure approval and provide the source of the approval.

If the submission is from an affiliate, the protocol must also be accompanied by documentation demonstrating the approval and consent for the study by the affiliate's board of directors. If submitted by the national organization, documentation must be from the standing committee or task force responsible for the proposal. Approved meeting minutes documenting such approval are sufficient. Responsibility for the execution and scientific integrity is shared among Prevent Blindness (and/or an affiliate), the principal investigator,

academic institution(s), and administrative officials within the sponsoring organization(s).

Receipt of a protocol for review will be acknowledged by Prevent Blindness.

C. Review/Approval

Committee members will have three weeks to review the protocol and supporting documents. In reviewing the protocol, committee members will consider the appropriateness of study design and methods, relevance to the Prevent Blindness mission, and likelihood of providing a significant contribution to the existing body of knowledge. In addition, the members must be satisfied that concerns for the safety and well-being of human subjects involved in the study have been met. Following consideration of the committee's comments, the committee will recommend approval, provisional approval or rejection of the protocol to the Prevent Blindness Board of Directors Chair.

When the committee is satisfied as to the scientific integrity of a proposed study, they may approve a protocol without reservation. Upon notification of approval, the submitter may commence study activities as described in the protocol.

When the committee is generally in favor of a protocol, but has reservations or desires revisions, the committee may provisionally approve the protocol. Upon notification of provisional approval, the submitter may address the concerns of the committee and resubmit the revised protocol for final approval. Study activities may not commence until the final approval of the designated review committee is given.

When the committee finds a protocol to be without sufficient scientific merit, they may reject the protocol. In this case, the proposed study generally suffers from major flaws in design, technique, or scope. Rejected studies may have insufficient support to achieve the stated goals, may lack an appropriate conceptual framework, or be of insufficient scientific significance. Rejected proposals may be revised and resubmitted for consideration, but are likely to require substantial changes.

D. Monitoring, Compliance, and Revocation of Approval

The committee is empowered to monitor the progress of approved studies and to check for compliance with the approved protocol. The committee may request progress reports from the investigator, including reports of adverse events as it deems necessary, including copies of annual Institutional Review Board reports. The committee may revoke approval of a study when the approved protocol is not observed or when serious adverse events occur. Revoked studies may not continue until approval is reinstated.

E. Study Completion and Publication

At the conclusion of the study, the principal investigator must notify the designated Prevent

Blindness committee. Any publications resulting from the study must acknowledge the participation of Prevent Blindness and copies must be provided to the committee.

F. Review Period

The review period, from the date of receipt of a protocol for review to the notification of its

approval status, shall not exceed eight weeks.

G. Approval Period

The approval status of a protocol is valid for the proposed period of the study described in the protocol plus one year. If a study is not commenced within three years of the notification of approval, the protocol must be resubmitted.

H. Documentation of Review and Approval

Documentation of the receipt, review, and approval status of all materials submitted to the designated Prevent Blindness committee will be maintained by Prevent Blindness for a period of three years after study completion or expiration of approval. The principal investigator is responsible for maintaining all other records relevant to the study for an appropriate length of time.

III. Research Advocacy

To build nationwide appreciation and support for the role of vision research in improving the quality of life for all Americans, Prevent Blindness mobilizes grassroots expressions of support to Congress for protecting and increasing National Eye Institute, Centers for Disease Control and Prevention, and other government agency funding for vision research. Prevent Blindness also values and supports eye research advanced by foundations and corporations. This and other research advocacy efforts are undertaken to the extent that they do not violate Prevent Blindness's policy regarding lobbying activity.

IV. Use of Animal Subjects, Human Subjects, or Fetal Tissue in Research

Use of animal subjects, human subjects, or fetal tissue in all Prevent Blindness research programs shall be governed by the relevant policies of the Association for Research in Vision and Ophthalmology to the extent that such policies have been established.

V. Research Restricted Funds

Unless otherwise designated, all funds received by affiliates and divisions that are restricted to research are presumed to be extramural and shall be exempt from the income and legacy sharing formulas and shall be forwarded within 30 days of receipt to the national office to support the nationwide Prevent Blindness Joanne Angle Public Health Award program (Board of Directors approval – February 1995).

No funds may be accepted by affiliates or divisions for the support of research projects (extramural or intramural) prior to the review and approval of the research protocol by the Public Health and Policy Committee or other committee as assigned. Funds for intramural research from any source shall be exempt from the extramural research restricted funds policy and shall continue to be includable income under the income and legacy sharing formulas.

VI. Policy History

Based on interest expressed by affiliates, the Board of Directors recommended that the Scientific Committee consider developing and administering a program designed to support applied research at the grassroots level (Board of Directors approval – February 1995).

At its April 1995 meeting, the Scientific Committee endorsed the nationwide policy permitting affiliate/division involvement in research contingent on the review, approval and monitoring of research protocols by the committee.

At its March 1996 meeting, the Scientific Committee established intramural research review and approval procedures.

In June 1997, the Board of Directors approved a revision that represented a compilation of diverse prior policies relating to the research activities of Prevent Blindness. To improve clarity, information from previous policy statements and other sources were combined, redundancies and outdated policies were deleted, and language was reworded where appropriate.

In July 2004, the Prevent Blindness Investigator Awards replaced the Fight for Sight program as Prevent Blindness's sole extramural research initiative.

In 2020, Prevent Blindness partnered with Fight for Sight to co-fund the Fight for Sight-Prevent Blindness Joanne Angle Public Health Award (suspending, for the time-being, the Prevent Blindness Joanne Angle Investigator Award pending future funding).

In July 2021, the board approved updated research approvals to be conducted by the appropriate Prevent Blindness committee (e.g., Scientific Committee, Public Health and Policy Committee, Center for Vision and Population Health Advisory Committee, and/or the National Center for Children's Vision and Eye Health).

VII. Policy Approval

This policy was approved by the Prevent Blindness Board of Directors on July 13, 2021.

Intramural Research Protocol Submission Form

Contact Name: _____

Affiliation: _____

Address: _____

Email: _____

Telephone: _____

Project Title: _____

Anticipated Project Dates:
From: _____
To: _____

Principal Investigator
Name: _____
Position: _____
Institution: _____
Address: _____
Email: _____
Phone: _____

Anticipated Funding Source: _____

Application Due Date: _____

Animal/Human Subjects: Yes/No
If yes, attach a copy of the Institutional Review Board Approval

With your application attach the following items:

- Budget: Include items such as personnel, equipment, supplies, etc.
- Principal Investigator CV or Biosketch

Project Description: Include goals and objectives, background and significance, subjects and methods