

National Neurovision Research Institute
Enhanced Career Development Award



FUNDING OPPORTUNITY ANNOUNCEMENT

**ENHANCED RESEARCH AND CLINICAL TRAINING FOR
PHYSICIANS IN INHERITED ORPHAN RETINAL DEGENERATIVE
DISEASES**

Deadline for Receipt of Applications: September 15, 2009

Address all inquires about this Funding Opportunity Announcement to:
grants@fightblindness.org

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National Neurovision Research Institute

Funding Opportunity Announcement (FOA)

Enhanced Research and Clinical Training for Physicians in Inherited Orphan Retinal Degenerative Diseases

PART I: Overview

1. Background and Objective

The National Neurovision Research Institute (NNRI) and the Foundation Fighting Blindness (FFB) are dedicated to supporting research to advance therapeutic and preventive strategies for inherited orphan retinal degenerative diseases into the clinic. Through the efforts of investigators supported by FFB and NNRI, substantial advances have been made in our understanding of these diseases, including genetic determinants, cellular, molecular and genetic mechanisms, cell-based therapeutic approaches, the role of nutrition and environmental factors, neuroprotection, and gene therapy strategies. With this enhanced knowledge, new treatment and prevention strategies are being developed and can now be tested in the clinical setting. In order to capitalize on current and emerging opportunities, NNRI recognizes the importance of and need to ensure an adequate supply of clinical scientists. This new program for enhanced research and clinical training is intended to support the recruitment and retention of a strong pool of physician/scientists with a commitment to clinical research on inherited orphan retinal degenerative diseases. The Program will provide support and protected time to individuals with M.D. and M.D./Ph.D. degrees for career development in clinical research related to inherited orphan retinal degenerative diseases leading to research and clinical independence.

2. Key Dates

Application Receipt Date: September 15, 2009

Earliest Anticipated Award Date: November 15, 2009

3. Executive Summary

- The goal of the NNRI enhanced research and clinical training program is to ensure that an adequate pool of highly trained physician/scientists is available to address current and future needs and opportunities for clinical research and therapy related to inherited orphan retinal degenerative diseases.

- Eligible applicants must (i) possess an M.D. or M.D./Ph.D. degree, (ii) hold a full-time tenure-track or equivalent appointment at the sponsoring institution with a commitment of no less than five (5) years, (iii) commit at least 80% of Full Time Equivalent (FTE) to the program, and (iv) have successfully completed an ophthalmology residency or equivalent training. For purposes of this Announcement and awards made pursuant to this Announcement, the definition of “FTE” in terms of weekly hours of effort will be that which is conventionally utilized by the sponsoring institution.
- Applications may be submitted on behalf of the candidate by domestic and foreign, public and private academic institutions and hospitals, as well as laboratories affiliated with such institutions.
- Awards will be for a project period of three (3) years with two options to extend the period of award for a fourth and a fifth year.
- Up to a total of \$170,000 per year may be requested to cover salary, fringe benefits and research support costs combined.

PART II: Program Description and Requirements

This Announcement solicits applications from qualified institutions and candidates for support of enhanced research and clinical training in inherited orphan retinal degenerative diseases. The program provides support and protected time for intensive career development in clinical research for individuals with M.D. and M.D./Ph.D. degrees. Award recipients must carry out a clinically-focused research project and a clinical training program for didactic and other forms of training that are tailored to meet the individual needs of the award recipient.

Section 1: Eligible Applicants and Percent Effort

Candidates with different levels of prior research training and experience and at different stages in their career development are eligible to apply.

1. **Eligible applicants must:**
 - a. have an M.D. or M.D./Ph.D. degree
 - b. have successfully completed an ophthalmology residency or equivalent training program
 - c. hold a full-time tenure track or equivalent appointment at the sponsoring institution with a commitment for five (5) years
 - d. commit at least 80% of Full Time Equivalent to the program.
2. Up to 20% effort is allowed for activities in other retinal specialties (e.g., vitreoretinal surgery, medical retina, etc.), but is not required.

3. Award recipients may reduce total effort to no less than 50% in the third year or, if approved by NNRI, in the fourth and fifth year of the award, and hold concurrent support from this program and a competing NIH or equivalent research grant **if** the research relates to inherited orphan retinal degenerative diseases and if the award recipient is recognized as a Principal Investigator (PI) or Subproject Director on the research grant. Any reduction in effort will require NNRI approval.

Section 2: Eligible Institutions

1. Applications may be submitted on behalf of candidates by domestic and foreign, public and private, academic institutions, as well as hospitals and laboratories affiliated with such institutions.
2. Sponsoring institutions must have a well-established record of research and career development relating to inherited orphan retinal degenerative diseases and provide a high quality research environment (including staff capable of productive collaboration), and the research facilities, resources and training opportunities necessary to carry out the enhanced research and clinical training program.
3. Sponsoring institution or Department must provide a five (5)-year commitment to the award recipient.

Section 3: Award Duration

1. Awards will be made for a project period of three (3) years with two options to extend the period of award for a fourth and a fifth year. Award extensions (i) will be contingent upon satisfactory progress and a meritorious career development plan for the extension period, (ii) will undergo peer review, and (iii) must be approved by NNRI.
2. Awards are not renewable.
3. Application resubmissions will not be accepted.

Section 4: Funds Available and Allowable Costs

1. Up to a total of \$170,000 for each year may be requested to cover salary, fringe benefits, and research support costs combined.
2. Research support costs may not exceed \$20,000 per year and may be used for (a) tuition and fees related to career development, (b) supplies, and technical personnel, (c) travel to research meetings and

training, and (d) statistical services, including personnel and computer time.

3. Indirect costs will not be provided.
4. Award recipients may retain other income, defined as fees for activities such as scholarly writing, service on advisory groups, honoraria from other institutions for lectures or seminars, and fees from clinical practice and professional consultation, provided that: (i) these activities do not interfere with the award recipient's committed level of effort to this program, (ii) these activities are not required by the research and training activities of this award, and (iii) the retention of such income is consistent with the policies and practices of the sponsoring institution.

Section 5: Research and Clinical Training Components

Award recipients must carry out a clinically-focused research project and a clinical training program with didactic and other forms of training tailored to meet the individual needs of the award recipient. Research projects and clinical training activities must focus on inherited orphan retinal degenerative diseases. Support will not be provided for research and clinical training relating to dry or wet age-related macular degeneration (AMD), retinal detachment, or vitreoretinal surgery.

1. Research Project:

- a. The research project must:
 - 1) have a clinical focus and address one or more inherited orphan retinal degenerative diseases
 - 2) have intrinsic value/research importance
 - 3) serve as a suitable vehicle for learning or enhancing knowledge of the methodologies, practices, guidelines and requirements for the design, development and conduct of research involving human subjects
 - 4) include timelines for each stage of the research project, i.e., design, implementation, completion and analysis, and, where appropriate, publication
- b. The types of research projects eligible for support include:
 - 1) clinical studies using human specimens, materials and/or data from diagnostic and other tests
 - 2) participation in clinical trials to evaluate the safety and efficacy of diagnostic, investigational therapeutic or preventive approaches/products

- 3) natural history studies
- 4) evaluations of the validity and reliability of patient assessment tools
- 5) translational research

For the purposes of this program, translational research is defined as the application of basic research discoveries to the diagnosis, management, treatment and prevention of human disease.

2. Clinical Training Program

Award recipients must pursue a systematic clinical training plan that provides for a logical progression from prior to enhanced training in clinical research related to inherited orphan retinal degenerative diseases and leading to research independence in this group of diseases. The Clinical Training Program must be tailored to the specific needs, level of training, experience, and career goals of the award recipient, and must include a schedule for the completion of all activities. Clinical training activities include formal courses and other forms of didactic training provided by the sponsoring institution and through other sources. Training activities may include a broad spectrum of topics, e.g.:

- a. the diagnosis, management, treatment and prevention of inherited orphan retinal degenerative diseases
- b. product development, including requirements for and sponsorship of Investigational New Drug (IND) Applications and Investigational Device Exemptions (IDEs)
- c. clinical protocol design, including hypothesis development, methodologies for statistical design and analysis, data and safety monitoring plans, and informed consent
- d. guidelines and regulatory requirements for the protection of human research subjects
- e. design and management of clinical research databases
- f. epidemiology and preventive medicine
- g. the responsible conduct of research
- h. grant writing
- i. publication of research results

Section 6: Program Evaluation and Reporting

1. **Progress Evaluation Plan:** Award recipients, in conjunction with collaborators and the Department Chair of the sponsoring institution, must implement a plan for evaluating progress and performance during the award period, including the criteria to be used to assess: productivity; the effectiveness of ongoing and completed training and other career development activities; progress in conducting the

research project; and interim and final outcomes/results of the research project.

2. **Annual Progress Reports:** Annual Progress Reports, based on the progress evaluation plan, must be submitted to NNRI within two (2) months of the completion of each year of the award period. Such reports must address the following:
 - a. **Clinical Training Program:** a description of clinical training activities completed during the prior funding period; an assessment of the performance of the award recipient in completed training activities; adherence to the schedule for clinical training activities; relevance of ongoing and completed training to the career development goals of the award recipient; and plans for additional training for the next year of support, including any proposed changes in the Clinical Training Program and their rationale.
 - b. **Research Project:** a description of status of the research project and progress in project design, implementation, conduct and analysis during the prior funding period, including a brief summary of any study results; any problems or obstacles encountered and approaches used to resolve or minimize such problems/obstacles; any proposed changes in study design and/or timelines and their rationale; and plans for continuation of the project for the next year of support.
 - c. a list of the accomplishments of the award recipient, e.g., publications, scientific presentations, new collaborations, inventions or resources developed during the prior funding period, and, if applicable, any research grant or contract support received from NIH or other funding sources.
 - d. any proposed change in the award recipient's percent effort, the rationale for the change, and the effect of any reduction in percent effort on the approved research project and/or clinical training activities.
 - e. a letter, signed by the Department Chair, to (i) confirm the continuing commitment of the sponsoring institution to the career development of the award recipient, including the provision of protected time at the approved level of effort and the institutional staff, facilities and other resources necessary to carry out research and training activities planned for the next year of support; and (ii) summarize the performance and accomplishments of the award recipient as evidence of adequate

progress toward achieving the stated career development goals and justification for continuation of the award.

- f. a breakdown of expenditures under the award for the prior year of funding to include: (i) salary; (ii) fringe benefits; and (iii) research support costs for tuition and fees related to career development, supplies, and technical personnel, travel to research meetings and training, and statistical services, including personnel and computer time.
3. **Final Report:** A Final Report detailing the research and clinical training activities undertaken, together with all accomplishments achieved, must be submitted to NNRI within two months of the end date of the award. The Final Report must include (i) an Executive Summary highlighting the major research and clinical training activities undertaken, the results of the research project, and the award recipient's future career plans, and (ii) a brief summary of the following:
- a. the career development goals of the award recipient
 - b. the clinical and research training activities completed and a discussion of how these activities contributed to enhancing the skills and capabilities of the award recipient in clinical research on inherited orphan retinal degenerative diseases
 - c. the research project undertaken and the results achieved
 - d. the award recipient's accomplishments during the award period, including publications, scientific presentations, inventions or project-generated resources developed, and research grant or contract support received from NIH or other funding sources
 - e. future career plans of the award recipient, including employment at the sponsoring institution or elsewhere, any additional research and career development activities, planned applications for research grant or contract support, etc.
 - f. a final expenditure report detailing all expenditures for the entire period of award, including: (i) salary; (ii) fringe benefits; and (iii) research support costs for tuition and fees related to career development, supplies, and technical personnel, travel to research meetings and training, and statistical services, including personnel and computer time.
4. **Long-Term Evaluation:** In order to carry out its stewardship of career development programs, NNRI may request information important to an assessment of the effectiveness of this program. Award recipients may be contacted after completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants and contracts, honors and awards, professional

activities, and other information useful in evaluating the impact of this program.

PART III: REQUIRED APPLICATION COMPONENTS AND INSTRUCTIONS

Application Formatting Instructions

All applications must conform to the following formatting requirements:

- Use an **Arial typeface and a font size of 11 points or larger**. (A Symbol font may be used to insert Greek letters of special characters; the font size requirement still applies.)
- Type density, including characters and spaces, must not exceed 15 characters per inch.
- Type may be no more than six lines per inch.
- Use standard letter size (8 1/2" x 11") sheets of paper.
- Use at least one-half inch margins (top, bottom, left, and right) for all pages.
- All page limits specified refer to single-spaced format using the above formatting requirements.

Application Submission Instructions

NOTE: The electronic version of the complete application must be received by September 15, 2009.

Submit an electronic copy of the complete application, either as a Word document or a PDF file, text-accessible, by e-mail to grants@fightblindness.org

In addition to the electronic version e-mailed to NNRI, mail one hard copy and a CD of the complete application to:

**ENHANCED RESEARCH AND CLINICAL TRAINING PROGRAM
National Neurovision Research Institute
11435 Cronhill Drive
Owings Mills, MD 21117-2220**

Required Application Components

All applications must include the information detailed below. Applications that do not provide all of the required information will be considered non-responsive and will not be reviewed.

Forms and templates for the preparation of applications are provided under PART IV of this announcement.

- 1. Application Face Page:** The Application Face Page must be completed and signed by the candidate, the Department Chair, and the authorizing official of the sponsoring institution. The Application Face Page of the electronic version of the complete application must be an **original PDF document, not a scanned copy** (i.e., a picture file converted to PDF format).
- 2. Table of Contents:** Provide a Table of Contents with page numbers for each major section of the application.

Section 1: Description of Enhanced Research and Clinical Training Program

- 1. Candidate** (not to exceed 4 pages exclusive of Department Chair letter and 3 letters of reference)
 - a. Describe the candidate's short- and long-term career goals.
 - b. Describe prior training and discuss how it relates to the objectives of this NNRI program and the candidate's short- and long-term career goals.
 - c. Describe prior research experience and discuss how it relates to the objectives of this NNRI program and the candidate's short- and long-term career goals. Include any work conducted on completed and ongoing research grants or contracts, the role of the candidate on such projects, and project results, publications, scientific presentations, etc.
 - d. Describe the candidate's current professional responsibilities at the sponsoring institution and elsewhere, if applicable. Include a description of the professional responsibilities and activities to be undertaken by the candidate beyond the 80% effort committed to the NNRI award, and explain how these responsibilities and activities will contribute to the candidate's further career development and ability to achieve research independence.

- e. Describe how the award will enable the candidate to devote more time and effort to clinical research and training relating to inherited orphan retinal degenerative diseases.
- f. Provide a letter, signed by the candidate, stating that he/she will commit at least 80% of Full-Time Equivalent effort to the research and clinical training activities specified in the application.
- g. Provide a letter, signed by the Department Chair of the sponsoring institution, addressing the following: (i) the performance of the candidate in his/her current position at the sponsoring institution; (ii) the candidate's potential to successfully pursue a productive career in clinical research on inherited orphan retinal degenerative diseases and to achieve research independence; and (iii) the commitment of the Department to the candidate's further career development, including providing necessary staff, facilities, equipment, other resources, and protected time at no less than 80% effort, to carry out the research project and clinical training program specified in the application. The letter from the Department Chair must also confirm that the candidate's appointment at the sponsoring institution is not contingent on the award of a grant under this NNRI program. For candidates moving from other institutions, provide a letter, signed by the original Department Chair, specifying: (i) the performance of the candidate in his/her current position; and (ii) the candidate's potential to successfully pursue a productive career in clinical research on inherited orphan retinal degenerative diseases and to achieve research independence
- h. Three (3) sealed letters of reference addressing the capabilities and potential of the candidate for a career in clinical research on inherited orphan retinal degenerative diseases. NOTE: Sealed originals of the letters of reference are to be submitted with the hard copy of the application.

2. Sponsoring Institution (not to exceed 4 pages)

- a. Provide documentation of a well-established research and training program related to inherited orphan retinal degenerative diseases, particularly with respect to the specific focus of the candidate's proposed research project and clinical training program. This includes documentation of a high quality research environment with staff capable of productive collaboration with the candidate and effective training in areas specified in the clinical training plan.

- b. Describe the staff, facilities, equipment and other resources that will be made available to the candidate for both the research project and the clinical training activities proposed.
- c. Provide a statement indicating the commitment of the sponsoring institution to a 5-year appointment for the candidate and to meet the requirements of this NNRI program.

3. Clinical Training Program (not to exceed 6 pages)

- a. **Clinical Training Plan:** Present a detailed and systematic plan that provides for the logical progression from prior to enhanced training in clinical research related to inherited orphan retinal degenerative diseases and leading to research and clinical independence. The plan must include the following:
 - 1) A description of the specific didactic and other forms of training to be undertaken by the award recipient, the source of each training course (i.e., sponsoring institution or other source), duration, and methods used to assess performance and certify successful completion.
 - 2) A discussion of how the clinical training plan is tailored to meet the specific career development needs, level of training and experience, and short- and long-term career goals of the award recipient, and how the plan utilizes the relevant educational resources of the sponsoring institution.
 - 3) A discussion of how the clinical training plan will enhance the productivity and promote the success of the award recipient as a clinical scientist, as well as provide the knowledge and skills necessary to launch an independent research career.
 - 4) A timeline for the initiation and completion of each component of the clinical training plan.
- b. **Other Specific Training Requirements:** The application must either document that the candidate has received prior instruction or propose plans for the candidate to receive instruction under this award on (i) the legal and ethical issues associated with research on human subjects, and (ii) the responsible conduct of research.
 - 1) Documentation of prior instruction must include: (i) a description of the subject matter of the courses completed; (ii) duration; (iii) source (i.e., sponsoring institution or other

source); and (iv) date of completion and certificate of completion.

- 2) Plans to receive instruction must include: (i) a description of the subject matter of the courses to be undertaken; (ii) duration; (iii) source (i.e., sponsoring institution or other source); and (iv) timeline for completion. At a minimum, subject matter must include: (i) scientific integrity; (ii) conflict of interest; (iii) responsible authorship; (iv) policies for handling misconduct; (v) informed consent; (vi) safety monitoring and reporting; (vii) policies for protecting the privacy of data on human subjects; and (viii) data management.

4. **Research Project Description** (not to exceed 15 pages exclusive of references and abstracts)

Note on Post-Award Requirement for Human Subjects Research:

Applications approved for funding and involving clinical research projects that require local IRB/IBC approval of the use of human subjects and, if applicable, the use of recombinant DNA, will require submission of documentation of such approval prior to release of funds.

- a. **Clinical Studies:** Applications proposing clinical studies, including studies using human specimens, materials and/or data from diagnostic and other tests, natural history studies, and evaluations of patient assessment tools, must provide the information specified below.

- 1) *Study Description:* Provide a detailed description of the proposed clinical study, including: (i) hypothesis and study objectives; (ii) study population(s) and relevance of the proposed study to clinical disease/patient outcome; (iii) study design, methodologies, and scientific rationale, including supporting data from completed basic, preclinical and clinical research, and the feasibility and appropriateness of applying such supporting data to the design and execution of the proposed clinical study; (iv) statistical analysis plan; (v) plan for management and quality control of study data; and (vi) plan for receipt and storage of human specimens and materials from diagnostic and other tests.
- 2) *Human Specimens, Materials and Data:* If applicable, provide documentation of the ability to acquire human specimens and materials from diagnostic and other tests prospectively or

retrospectively, including specimens and materials to be obtained from planned, ongoing, or completed clinical studies/trials sponsored by any source of support. If data from patient registries and/or other existing sources are to be used, identify each source, provide a thorough description of the patient data available and the time period covered by each database, and detail any additional patient data to be collected for the proposed study. Include a copy of any written agreements between the applicant institution and the clinical study/trial sponsor, IND/IDE sponsor or source of patient data for the provision of human specimens, other materials and patient data necessary for the conduct of the proposed study.

- 3) *Informed Consent*: For ongoing studies, provide a copy of the approved informed consent used for the prospective collection of human specimens, other materials and data, or for the use of existing human specimens, other materials and data. For planned studies, a copy of the informed consent and proof of local IRB approval shall be required prior to study implementation.
- 4) *Timelines*: Describe the major steps or stages of the clinical study to be carried out and provide proposed timelines for their initiation, execution and completion, including the timelines for clinical study completion and analysis of final study data.
- 5) *Description of Candidate's Participation*: Describe the proposed role of the candidate in clinical study design, execution and analysis, and discuss how his/her participation is expected to develop the knowledge and skills necessary for a productive and independent career in clinical research related to inherited orphan retinal degenerative diseases.
- 6) *Collaboration/Supervision*: Identify the Principal Investigator for the clinical study, any other collaborators and their role in study design and execution, and the individual with primary responsibility for overseeing the candidate's participation in the clinical study. In addition, discuss plans for ensuring appropriate supervision and the further development of the candidate's knowledge and skills relating to clinical research. **NOTE**: CVs for supervisory personnel and collaborators are to be provided under Section 5 of the application.
- 7) *References*: Provide a list of up to five references and abstracts for publications relevant to the data cited to support the scientific rationale of the proposed clinical study.

- b. **Clinical Trials:** Applications proposing participation of the candidate in planned or ongoing clinical trials must provide the following:
- 1) *Clinical Trial Description:* For both planned and ongoing clinical trials, provide a detailed study description addressing the key design features delineated below. **NOTE:** Applications should not provide full clinical protocols either in development or final.
 - a. hypothesis, study objectives, and scientific rationale, including supporting data from completed research, and study population(s);
 - b. statistical design, including eligibility/exclusion criteria; randomization/stratification plan, sample size and justification, primary and secondary endpoints/outcomes, laboratory and diagnostic evaluations, and statistical analysis plan;
 - c. plans for the collection, storage and quality control of study data and human specimens and other materials;
 - d. safety monitoring plan;
 - e. clinical trial status (i.e., in development, pending regulatory review and approval, open to enrollment, etc.), and timelines for study execution, completion and analysis of final data; and
 - f. IND/IDE sponsorship and arrangements for the provision of investigational product(s)/device(s).
 - 2) *Description of Candidate's Participation:* Describe the proposed role of the candidate in clinical trial design, execution and analysis, and discuss how his/her participation is expected to develop the knowledge and skills necessary for a productive and independent career in clinical research related to inherited orphan retinal degenerative diseases.
 - 3) *Collaboration/Supervision:* Identify the Principal Investigator for the clinical trial, any other key collaborators, and the individual with primary responsibility for overseeing the candidate's participation in the clinical trial. In addition, discuss plans for ensuring appropriate supervision and the further development of the candidate's knowledge and skills relating to clinical research. **NOTE:** CVs for supervisory personnel and collaborators are to be provided under Section 5 of the application.

- 4) *References*: Provide a list of up to five references and abstracts for publications relevant to the data cited to support the scientific rationale of the clinical trial.
- c. **Translational Research Projects**: All proposed translational research projects must meet the definition of translational research, i.e., the application of basic research discoveries to the diagnosis, management, treatment and prevention of disease. Applications must provide a detailed description of the proposed translational research project addressing the following:
- 1) *Specific Aims and Clinical Relevance*: Describe the specific aims of the proposed translational research project and its potential relevance/value in terms of facilitating/advancing diagnostic, therapeutic and preventive interventions for inherited orphan retinal degenerative diseases into the clinic. Specifically discuss the feasibility of applying the results of the proposed translational research project to the development of new or improved clinical interventions.
 - 2) *Scientific Rationale, Experimental Design, and Methods*: Discuss the scientific rationale for the proposed translational research project, including supporting data, if available, from ongoing and/or completed research, to demonstrate the soundness and feasibility of the proposed experiment(s). Include a detailed description of the experimental design and methods to be used.
 - 3) *Timelines*: Describe the major steps or stages of the translational research project to be carried out and provide proposed timelines for their initiation, execution and completion, including the timelines for study completion and analysis of final study data.
 - 4) *Description of Candidate's Role*: Describe the proposed role of the candidate in the design, execution and analysis of the translational research project, and discuss how his/her participation is expected to develop the knowledge and skills necessary for a productive and independent career in clinical research related to inherited orphan retinal degenerative diseases.
 - 5) *Collaboration/Supervision*: Identify the individual with primary responsibility for overseeing the candidate's conduct of the translational research projects, and discuss plans for ensuring appropriate supervision and the further development of the

candidate's knowledge and skills relating to translational research. Also identify any study collaborators and describe their role in the research project. **NOTE:** CVs for supervisory personnel and collaborators are to be provided under Section 5 of the application.

- 6) *References:* Provide a list of up to five references and abstracts for publications relevant to the data cited to support the scientific rationale for the translational research project.

Section 2: Progress Evaluation Plan (not to exceed 3 pages)

The application must provide a plan for evaluating the candidate's progress and performance during the award period, including the criteria to be used to assess: (i) productivity; (ii) the effectiveness of ongoing and completed training and other career development activities; (iii) progress in conducting the research project; and (iv) research project interim and final outcomes/results. The Progress Evaluation Plan must be in sufficient detail to allow for a comprehensive assessment of the value and appropriateness of the training and research activities undertaken, and to provide adequate justification for continuation of the award beyond the first year.

Section 3: Plans for Sharing Research Data and Research Resources (not to exceed 2 pages)

NNRI requires award recipients to share research data and research resources generated under this award. Therefore, all applications must include (i) a plan for sharing research data, and (ii) a plan for sharing research resources resulting from or utilized in the research projects supported.

1. The *Plan for Sharing Research Data* should specify the methods to be used to disseminate the results of the research project to the scientific community, including scientific publications, abstracts, presentations at scientific meetings, etc.
2. The *Plan for Sharing Research Resources* should specify the methods to be used to make research resources developed under this award readily available for research purposes to qualified individuals within the scientific community after publication.

Section 4: Budget

The application must include a budget providing a breakdown of (i) total annual costs requested for years 1, 2 and 3, and (ii) the total budget requested for the

entire 3-year period of support. The budget is to be prepared using the form provided under Part IV of this announcement.

Section 5: Curricula Vitarum

The application must provide CVs for the candidate and for the individuals listed below. Limit CVs to 3-4 pages, include qualifications, expertise and experience relevant to training of M.D.s and M.D./Ph.D.s in general and with respect to clinical research related to inherited orphan retinal generative diseases, and include qualifications, expertise and experience relevant to the proposed research project.

1. Department Chair
2. personnel of the sponsoring institution with responsibility for didactic and other training courses, and personnel for training courses conducted by other organizations/institutions
3. individual responsible for supervision of the candidate in carrying out the research project
4. any proposed research project collaborators

Section 6: Letters of Reference

Attach three (3) sealed original letters of reference for the candidate under Section 6 of the hard copy of the complete application that is mailed to NNRI. .

PART IV: APPLICATION FORMS AND TEMPLATES

Applications are to be prepared using the specific forms and templates that accompany this announcement with information presented in the order indicated.