FOUNDATION FIGHTING BLINDNESS

Harrington Discovery Institute

University Hospitals | Cleveland Ohio

The Gund-Harrington National Initiative For Fighting Blindness

Request for Proposals

Application Package

Contents:

The Gund-Harrington National Initiative
For Fighting Blindness

Request for Proposals

GOAL:
The goal of The Gund-Harrington National Initiative for Fighting Blindness (GHI) is to accelerate translation of research findings in the inherited retinal degenerative diseases (IRD) with the ultimate goal of developing new therapies to improve and/or restore vision.

The initiative is collaboration between the Foundation Fighting Blindness (FFB) and the Harrington Discovery Institute. The goal of developing new therapies will be achieved by providing award recipients with both research funding and guidance in drug development.

The Initiative is overseen by The National Center for Excellence in Fighting Blindness: A Gund-Harrington Initiative, based within University Hospitals in Cleveland, Ohio.

SCOPE:
This Initiative seeks to award Gund-Harrington Scholar Awards that recognize innovators throughout the USA whose research has the potential to change standards of clinical care.

There will be an average of three awards per year, which will be restricted to researchers working at institutions within the USA. Applications from outside the USA are not accepted.

The Gund-Harrington Scholar Award provides funding for translational drug development and cell therapy along with non-financial project support to help bridge the gap between laboratory-based research and the clinic.

Funding up to a total of $900,000 over three years is provided. The non-financial support will consist of guidance provided by a team drawn from the Harrington Discovery Institute Innovation Support Center which will include project management and experienced industry advice in all aspects of drug development, encompassing chemistry, formulation, toxicology, regulatory, intellectual property and business development.

Awards will be made to physician-scientists, or scientists with a research team that includes significant involvement of a physician with clinical expertise in the IRD.

Selected projects must demonstrate a reasonable expectation that they can develop a lead product[1] with strong potential for clinical and commercial application by the end of the three year funding period.

[1] Hefti F, "Requirements for a lead compound to become a clinical candidate", *BMC Neuroscience* 2008, 9(Suppl 3):S7

Gund-Harrington Scholar Award projects should have the following characteristics:

- Innovative science that addresses a significant opportunity leading to treatment or prevention of inherited retinal degenerative diseases (IRD).
- The potential to be developed into a commercial product.
- Development of a small molecule or biologic
- Diagnostics are only acceptable if linked to a therapeutic product

Multi-disciplinary investigators outside the field of retinal disease are particularly encouraged to apply.

Applications are invited in **any** area relevant to the treatment of inherited retinal degenerative diseases (IRD) that addresses this field. In most cases, device development is not supported.

Areas of **particular interest** include:

- Therapies for treatment strategies that are not gene specific, but might be broadly applicable across many patients
- Therapies that may be effective in later stages of disease
- Therapies developing gene delivery vectors or gene modifying strategies that can be used as a general platform to target specific retinal cell types, deliver/correct genes with large coding regions, specifically target outer retinal cells and impact cells across the entire retinal area
- Therapies that address juvenile macular degeneration
- Regenerative medicine therapies that focus on stem cells differentiated into photoreceptor cells
- Therapies based on novel targets

APPLICATION TIMELINE:

Process:

To apply for an award, applicants should submit a letter of intent and curriculum vitae, as outlined below. Those applications chosen for further review will be invited to submit a full application.

1. **Letters of Intent and Curriculum Vitae:**
   A non-binding letter of intent in response to this request for proposals, and curriculum vitae, must be received no later than midnight EST, **December 3, 2014.** There is no specific application form for this information: see instructions below.

2. **Final applications:**
   When invited, final applications must be received no later than midnight EST, **March 9, 2015.** Applications must be made using the appropriate Gund-Harrington Scholar Application Forms included in this package and available on the FFB website www.FightBlindness.org and HDI website: http://www.uhhospitals.org/services/harrington-discovery-institute

Awards are expected to be announced in **May 2015.**

DESCRIPTION OF FUNDING:
The awards are provided as milestone-driven payments totaling up to $900,000 over a three year timeframe. Up to 10% of the award may be requested as an upfront payment at the start of the award. Subsequent award payments will be made after the first milestone is completed and progress reviewed by the Foundation Fighting Blindness and Harrington Discovery Institute scientific teams and the drug development experts of the Harrington Discovery Institute's Innovation Support Center.

Applications and award budgets should be built around key milestones. Milestones are key points in a project which represent reliable, quantifiable indicators/deliverables of the project's progress, and are used to make decisions on further progress. The simple completions of tasks, or the passage of time, are not acceptable milestones. If an award is made, the Harrington Discovery Institute Innovation Support Center will work with recipients to help refine and manage the milestones.

The project must be structured to deliver a lead product with strong potential for clinical and commercial application.

The awards are conditional on your meeting certain obligations and deliverables including:

- Willingness to work collaboratively with the HDI Innovation Support Center staff
- Timely submission of financial and progress reports
- Participation in an annual Foundation Fighting Blindness-Translational Research Acceleration Program (FFB-TRAP) Symposium organized by the Foundation Fighting Blindness
- Participation in an annual Scientific Symposium, organized by the Harrington Discovery Institute in Cleveland, Ohio on May 20-21, 2015

Awards may be terminated at any time. Continued support is dependent upon favorable scientific review of progress reports, milestones being met appropriately, and continued relevance of the work to the mission of the Foundation Fighting Blindness.

Applicants and their institutional officials for sponsored programs must review the Award Agreement prior to submission. Institutions must certify that the terms of the award agreement are acceptable, at the time of submission of an award application; however institutions should not sign the actual Award Agreement until a final funding decision is made. Successful applicants must deliver fully executed Award Agreements within 30 days of notification of an award. Failure to meet this requirement may lead to withdrawal of the award offer.

National Center for Excellence in Fighting Blindness:
A Gund-Harrington Initiative

Application Instructions

Process:
To apply for an award, applicants should first submit a letter of intent and curriculum vitae, as outlined below. Those applications chosen for further review will be invited to submit a full application as outlined below.

Letter of Intent:
The Letter of Intent (not to exceed two pages using Arial 11pt font) must include on the first page:

1. The title of the research project;
2. The therapeutic approach and current state of knowledge of the lead compound
3. The inherited orphan retinal degenerative disease population this research impacts and the potential clinical benefit if it is fully developed
4. The overall goal, list of milestones proposed, and general rationale for the research proposed.

Curriculum Vitae:
Curriculum vitae for the Principal Investigator (PI) and all co-PI's must accompany the Letter of Intent. No specific format is required, but the NIH biosketch format is encouraged. Do not exceed four pages for each curriculum vita.

Full Application:
The full application must consist of the following sections:

Face Page – complete all sections of the Face Page provided in the Gund-Harrington Initiative-TRAP application package.

Please insert a Header on every page that contains the PI's name and Project Title

SECTION 1. ABSTRACT (*limit 1 page*)
Provide an abstract of the proposed research project, written in lay terms for a non-scientific audience. The abstract should contain non-confidential material that can be posted publicly if the application is funded.

The Abstract should describe:

- The goal of the research
- The IRD population who might benefit
- The clinical significance of the proposed research
- What is novel and innovative about the proposed research
- The nature of the collaboration(s) proposed and the strength it brings to the research;

- A brief description of all goals and related milestones, including concise outlines of the experimental approaches required to achieve them and the final deliverables;

SECTION 2. SPECIFIC GOALS AND RATIONALE (*limit 1 page*)
Describe the overall goal(s), associated milestones, and rationale for the proposed project. Describe the potential clinical value of the proposed research in terms of developing treatments for the IRD and the patients most likely to benefit from the therapy. Note any wider disease indication that may also benefit from the proposed therapy.

SECTION 3. PRELIMINARY/SUPPORTING DATA (*limit 3 pages*)
Describe the background to the proposed research including existing experimental data and/or prior research that supports the soundness and feasibility of the proposed experiments and describe how they support the validity of the approach proposed and support translation towards clinical and commercial application.

SECTION 4. DETAILED PROJECT DESCRIPTION (*limit 5 pages*)

1. Experimental Plan and Methods:

This section must be structured around goal-oriented milestones. Milestones should be spaced according to the needs of the project, but no two milestones should be more than 12 months apart. For each milestone:

- State the milestone in precise, quantifiable terms;
- Explain the practical importance and value of each milestone to the progress of the project;
- Provide the quantitative or qualitative criteria by which the successful completion of each milestone should be judged by the Gund-Harrington Initiative;
- Provide the clear deliverable(s) associated with the milestone;
- Describe the experimental design, procedures and methods to be used and discuss alternative strategies that may be required to achieve the milestone and deliverable(s).

Applicants must include sufficient information for reviewers to understand the proposed experiments, soundness, feasibility and importance for translating the proposed therapeutic approach into clinical application.

2. Timelines:

Provide a milestone-based timeline for the proposed research. Applicants are encouraged, but not required, to use a Gantt chart, which can be generated with Microsoft Project or similar software. However, the final output included in the application must be in Adobe pdf format.

3. Collaborative Plans:

Applications should describe any collaborative plans and the strengths each collaborator brings to the project. If the applicant is not an M.D. or equivalent, a collaborating clinician is required – provide the clinician's address and affiliation and explain how that physician will be involved and the specific skill sets they will contribute. Provide letters of collaboration stating the support and sharing that will take place in the Appendix Materials.

Applications should outline specific areas of the proposal where input from the Harrington Discovery Institute's Innovation Support Center would be particularly needed, such as in medicinal chemistry, formulation, toxicology, drug metabolism and pharmokinetics, etc.

4. Intellectual Property (IP) Impact:

Discuss the current status of any relevant IP

SECTION 5. HUMAN, ANIMAL, AND RECOMBINANT DNA STUDIES

Prior to funding certification of the following will be required, as applicable:

1. Institutional Review Board (IRB) approval if the application involves human subjects;
2. A copy of the approved or proposed informed consent form to be used for collection of patient samples if proposed;
3. Institutional Biosafety Committee (IBC) approval if the application involves the use of recombinant DNA;
4. Institutional Animal Care and Use Committee (IACUC) approval if the application involves the use of live vertebrate animals;
5. Evidence of Health Insurance Portability and Accountability Act (HIPAA) compliance, if applicable; and,
6. Evidence of compliance with the requirement for education in the protection of human research participants.

Evidence of IRB, IACUC, and IBC approval must be documented at the time of submission of a signed Gund-Harrington Initiative Institutional Agreement Form (IAF). If approvals are pending at the time of award, Gund-Harrington Initiative funding cannot be used for research involving human subjects, recombinant DNA, and live vertebrate animals until documented approval is submitted to the Gund-Harrington Initiative.

In addition, applications proposing research using human samples or subjects must provide documentation of the ability to acquire human samples prospectively or retrospectively, including obtaining samples from planned, ongoing or completed clinical studies/trials sponsored by any source must be provided. This must include written agreements between the applicant institution, the clinical trial sponsor, and the Investigational New Drug (IND) or Investigational Device Exemption (IDE) sponsor, if the applicant is not one of the above, for the conduct of the proposed study. **Exception:** If IRB approval is not required in order to conduct the proposed clinical study using human samples, then projects are considered non-clinical and applicants are not required to provide this information.

SECTION 6. REFERENCES

Provide a list of references and/or abstracts for:

1. Publications cited to support the scientific research proposal
2. Up to **five** pertinent reprints representing the applicant's research. This information does **not** count against the page limits.

SECTION 7. BUDGET (*limit 2 pages*)
Applicants **must** use the Gund-Harrington Initiative Budget Form. This form is provided as an Excel template embedded within Word (double click the Word table to enter information) in the Grant Application Package. In the application package, the budget must be submitted as a separate Excel file.

The award budget must be built around the cost associated to achieve each milestone. A proposal containing a budget based on yearly costs or regularly dispersed payments will not be accepted.

An initial payment of ten percent (10%) of the total budget may be requested up front, to be paid upon initiation of the approved project. The use of this money should be justified as part of the cost to reach the first milestone. Subsequent payments should be budgeted as milestone payments and will only be made when the Gund-Harrington Initiative determines that the relevant milestone has been met satisfactorily.

Budget Limitations:

1. Requested budgets must not exceed $900,000 over a three year timeframe.
2. The support requested for the Principal Investigator must not exceed **twenty percent** (**20%**) of the total budget.
3. The award may be used to support the salaries of research trainees (graduate students, postdoctoral or clinical fellows), technical staff and research supplies.
4. Purchase of significant equipment is generally not supported by the Gund-Harrington Initiative. Significant equipment is defined as permanent or semi-permanent apparatus, devices or systems costing more than $5,000 per item or system. Applicants **must obtain prior approval** from the Foundation Fighting Blindness to submit an application proposing to purchase equipment. All such equipment purchase requests must be well justified in the budget section of the application and in the description of proposed project.
5. The Gund-Harrington Initiative does not pay indirect or overhead charges, nor does the Initiative provide support for building construction or renovation.
6. Final approved budgets may be restructured post-award based on ISC recommendations

Budget Application:
Provide a budget for the achievement of each time-dependent milestone, itemizing:

1. Personnel support, listed by name and degree with percent effort, salary, and fringe benefits requested;
2. Supplies, itemized by general category, *e.g.* glassware, molecular biology reagents;
3. Patient Costs, itemized by number of patients and per patient cost;
4. Animal Costs, itemized by number, type, and length of housing;
5. Include travel costs of **$1,500** per 12 month period for the required attendance at the annual FFB-TRAP Symposium;
6. **DO NOT** include travel costs for the required attendance at the annual Harrington Discovery Institute Symposium. Those costs will be covered separately by the Harrington Discovery Institute;

7. Travel funds up to $2,000 may be requested for meetings and conferences outside the two listed above;
8. Other costs should be clearly itemized.

Budget Justification:
Provide a justification for the budget requested for each of the above categories.

For "Personnel Support" justification:

- List all scientific and technical personnel involved in the proposed project;
- Clearly designate roles of all personnel;
- Clearly identify key personnel and co-investigators;
- Provide a current NIH biosketch or equivalent for all key personnel;
- For each person identified as key personnel provide information on all other sources of financial support, including both current and proposed projects. For each source (federal, private or commercial) provide:
    - Title of grant/award;
    - Grant/award number;
    - Percent effort;
    - Funding amount;
    - Budget period;
    - A short description of the project's goals.

SECTION 8. APPENDIX MATERIALS
In the Appendix include:

1. Letters of Collaboration for all proposed collaborators which describe the type of collaboration and support being provided.
2. Reprints submitted as supporting documentation. Each reprint should be provided individually in pdf format.

SECTION 9. ADDITIONAL INFORMATION

Eligibility:
Applicants must be physician-scientists (M.D.; M.D., Ph.D.; or equivalent) or scientists with a research team that includes significant involvement of a physician with clinical expertise in the IRD.

Multi-disciplinary investigators outside the field of retinal disease are particularly encouraged to apply.

Applications from outside the USA are not accepted.

Applicants from academia must hold a faculty position or equivalent at a college, university, medical school, or other research institution in the USA. Applications may be submitted by domestic non-profit organizations, both public and private, such as universities, colleges, institutions, hospitals, and laboratories.

Applications from for-profit biotechnology companies may be eligible to apply but must enquire about eligibility **before submitting an LOI**, by sending a short synopsis about the company and their proposed project to grants@fightblindness.org.

Reports:
Upon completion of a milestone a **milestone scientific report** and a **milestone financial report** are required, along with a request for the milestone payment. Scientific milestone reports are required within 14 days of completing the experiment(s) associated with the milestone. Reporting of outcomes to the Gund-Harrington Initiative cannot be postponed while waiting for publication.

Short **progress reports** may also be requested from time to time to help the Gund-Harrington Initiative in its assessments and to meet other operational needs of the Foundation Fighting Blindness and the Harrington Discovery Institute. These must be provided promptly when requested.

In addition to written reports, the Gund-Harrington Scholars are required to collaborate with the Harrington Discovery Institute Innovation Support Center team assigned to the grant.

Annual Assessment:
Each Principal Investigator is required to attend two annual symposia – the FFB -TRAP Symposium organized by the Foundation Fighting Blindness and the Harrington Discovery Institute Scientific Symposium – to present their work and discuss progress.

Inquiries:
The Gund-Harrington Initiative welcomes the opportunity to clarify any issues or questions from potential applicants regarding this funding program. To avoid submission complications, the Gund-Harrington Initiative encourages questions well in advance of the submission deadlines. Please direct all inquiries to the Director, Grants and Award Programs of the Foundation Fighting Blindness at grants@fightblindness.org.

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 or 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 ½" 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 March 9, 2015.

The application should be submitted as two files. The first, a single text-accessible PDF file that contains:

- the face page
- Sections 1 to 9 (excluding the Budget worksheet but including the budget justification),

The second, an EXCEL file containing the completed budget worksheet. Do not convert this file to pdf.

E-mail applications to the Executive Assistant, Gund-Harrington Initiative (grants@fightblindness.org). If a receipt of confirmation is not received within 48 hrs please contact the Gund-Harrington Initiative at grants@fightblindness.

If you are having difficulty submitting your application, please contact the Gund-Harrington Initiative, at grants@fightblindness.org for assistance or alternate arrangements.

Applications failing to meet these guidelines will not be reviewed.

The Gund-Harrington Initiative **Face Page**	**For** Gund-Harrington Initiative **Use Only**	**Rec'd:**
	Rev'd:	**Award:** ☐**Yes** ☐**No**
	Term:	**Amount:**

Title of Project:

Principal Investigator

PI Name: (last, first, middle initial):	**Address:** (street, city, state, zip)
Degrees:	
Title:	
Dept:	**E-Mail:**
Institution:	**Ph:** **FAX:**

Conflict of Interest	**Stem Cells**
Do you have any commercial financial interest in the molecule or studies? ☐Yes ☐No	Does this research use stem cells? ☐Yes ☐No ☐Human ☐Embryonic ☐Fetal ☐Adult ☐Umbilical/Cord Blood

Human Subjects, Animal Welfare and Recombinant DNA

Human Subjects ☐Yes ☐No **Clinical Trial** ☐Yes ☐No **If Yes, Human Subjects Assurance #**	**Vertebrate Animals** ☐Yes ☐No **If Yes, IACUC app'l date:** **If Yes, Animal Welfare Assurance #:**	**Does this involve recombinant DNA?** ☐Yes ☐No **If Yes, IBC approval received?** ☐Yes ☐No

Term/Budget

Proposed Total Period of Support: (Month/Year-Month/Year):

Total Budget Requested:

Disease & Research Area Categories – For tracking purposes, please indicate:

Which **diseases** are of **primary focus**?

☐ Dominant Retinitis Pigmentosa	☐ Stargardt Disease
☐ Leber Congenital Amaurosis	☐ Usher Syndrome
☐ Recessive Retinitis Pigmentosa	☐ X-linked Retinitis Pigmentosa
☐ Retinitis Pigmentosa	☐ Other – Specify ____

Key Words (max of three): 1)	2)	3)

Grant Administrator to be Notified of Award	**Official Signing for Applicant Organization**
Name:	**Name:**
Title:	**Title:**
Address:	**Address:**
Ph: **FAX:**	**Ph:** **FAX:**
E-mail:	**E-Mail:**

Applicant Organization Acceptance of the Gund-Harrington Initiative Award Agreement: I certify that I have read the Gund-Harrington Initiative Award Agreement in entirety, including Exhibit E entitled "Foundation Fighting Blindness Patent Policy", and certify that the terms of this agreement are acceptable if an award is made as a result of this application.	**Signature of Official Named Above:** **Date:**
Applicant Organization Certification and Acceptance: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with the Gund-Harrington Initiative terms and conditions if a grant is awarded as a result of this application. I am aware that false, fictitious or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	**Signature of Official Named Above:** **Date:**
Principal Investigator/Program Director Assurance: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Gund-Harrington Initiative terms and conditions if a grant is awarded as a result of this application. I am aware that false, fictitious or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	**Signature of Principal Investigator:** **Date:**

Gund-Harrington Initiative Face Page 2		
Applicant Name:		
Title of Project:		
Collaborating Clinician Scientist (when PI is not M.D. or equivalent)		
Name: (last, first, middle initial):	**Address:** (street, city, state, zip)	
Degrees:		
Title:		
Dept:	**E-Mail:**	
Institution:	**Ph:**	**Fax:**
Signature:	**Date:**	
Sponsoring Dean or Department Chair		
Name: (last, first, middle initial):	**Address:** (street, city, state, zip)	
Title:		
Dept:	**E-Mail:**	
Institution:	**Ph:**	**Fax:**
Signature:	**Date:**	

BUDGET FORM

Instructions to complete Budget using the embedded Excel Template (next page):

- *Activate the Excel version of the template by double clicking anywhere within the table*
- *Complete the budget with the requested information.*
- *When possible use formulas (e.g. SUM) for totals.*
- *Insert additional rows if necessary*
- *You can return to the Word version at any time by clicking outside of the Excel box*
- *The document can be saved at anytime in either Word or Excel versions. Only the Excel version of the budget should be submitted, as a separate file, with the completed application.*

Gund-Harrington Initiative
BUDGET

Name of Project:

Name of Principal Investigator:

Co-Investigators:

	Milestone 1 mm/dd/yy-mm/dd/yy	Milestone 2 mm/dd/yy-mm/dd/yy	Milestone 3 mm/dd/yy-mm/dd/yy	Milestone 4 mm/dd/yy-mm/dd/yy	Milestone 5 mm/dd/yy-mm/dd/yy	PROJECT TOTAL
Budget Category						
Personnel						
(Name, Degree, & Title)						
(Salary + Fringe; % Effort)						
Total Personnel						
Supplies (Itemize)						
Total Supplies						
Patient Costs (Itemize)						
Total Patient Costs						
Animal Costs (Itemize)						
Total Animal Costs						
FFB TRAP Travel (3 trips)	N/A	N/A	N/A	N/A	N/A	$4,500
Other Travel (# Trips)	N/A	N/A	N/A	N/A	N/A	
Total Travel Costs						
Other Costs (Itemize)						
Total Other Costs						
TOTAL						

Award Agreement:

The Award Agreement for the Gund-Harrington Scholar Award is provided on the following pages. Any changes requested in the terms of the agreement should be addressed with the Foundation Fighting Blindness (grants@fightblindness.org) prior to submission of the final application

Applicants and their institutional officials must review the Gund-Harrington Initiative Award Agreement prior to submission. Institutions must certify on the Face Page of this application that the terms of the Award Agreement are acceptable, at the time of submission of an award application, but are not required to sign the actual agreement at that time. If an award is made, the Gund-Harrington Initiative approved milestones and budget will be entered into the agreement, which must be fully executed and delivered to the Gund-Harrington Initiative within 30 days of notification of an award. Failure to meet this requirement may lead to withdrawal of the award offer.

THIS IS A SAMPLE AGREEMENT ONLY
Terms and Conditions included here may differ from those included with invitations for full application.

Gund-Harrington Initiative Award

AWARD AGREEMENT[2]

Date: <MONTH, DAY, YEAR>

Award Recipient/Principal Investigator: <FIRST, INITIAL, LAST, DEGREE>

Sponsoring Institution <NAME>

Address: <ADDRESS>

Project Title: <PROJECT TITLE>

Award Number: <AWARD NUMBER> (to be completed by GHI staff)

Award Term: <NUMBER (X) YEARS> (to be completed by GHI staff)

The Gund-Harrington Initiative hereby approves the Application (as defined below) for funding as follows, upon the terms and conditions set forth in this Award Agreement in accordance with approved project and project budget attached as Exhibit A:

Total: **Up to $<Enter Value>** (All amounts include 0% indirect costs)

Payment of the Award is contingent on the Award Recipient and Sponsoring Institution (individually and collectively **"Awardee"**) executing this Award Agreement, meeting certain Milestones, which are specified in Exhibit B, and timely compliance with the reporting requirements specified in this Award Agreement and is otherwise subject to the terms and provisions of this Award Agreement.

1. Definitions.

(a) **Agreement** shall mean this Award Agreement.

(b) **Applicable Law** shall have the meaning set forth in Section 13.

(c) **Application** shall mean the application submitted to the Gund-Harrington Initiative and executed by the Principal Investigator and the Sponsoring Institution, a copy of which is attached hereto as Exhibit A and incorporated by reference herein.

(d) **Approved Budget** shall mean the budget(s) in the approved Application attached hereto as

[2] This agreement is not an official notification of award but intended for the purpose of communicating to the applicant and applicant's institution the terms and conditions of this program in the event an award is offered.

Exhibit A.

(e) **Award** shall mean the funding provided under, pursuant to, and in accordance with, this Award Agreement.

(f) **Award Funds** shall mean the monies received under this Award Agreement.

(g) **Award Information** shall mean the results, data, records, work product or Invention created in connection with the Award Research.

(h) **Award Research** shall mean research conducted pursuant to this Award Agreement as described in the Application**.**

(i) **Award Term** shall have the meaning set forth in the preamble of this Award Agreement.

(j) **Award Invention** shall have the meaning set forth in FFB's Patent Policy, attached hereto as Exhibit E.

(k) **Confidential Information** shall have the meaning set forth in Section 19**.**

(l) **FFB** shall mean the Foundation Fighting Blindness

(m) **Final Reports** shall have the meaning set forth in Section 4. The form of the Final Report template is attached hereto as Exhibit C and may be amended from time to time by the Gund-Harrington Initiative. The Gund-Harrington Initiative will supply the most current form of the Final Report template in electronic form as needed.

(n) **GHI** shall mean the Gund-Harrington Initiative

(o) **GHI-TRAP** shall mean the Gund-Harrington Initiative Translational Research Acceleration Program of the Foundation Fighting Blindness

(p) **HDI** shall mean the Harrington Discovery Institute

(q) **IRB** shall mean the Institutional Review Board of the Sponsoring Institution.

(r) **ISC Committee** shall mean the Innovation Support Center of the Harrington Discovery Institute and any subcommittee of the Innovation Support Center, which may also include a representative of the Foundation Fighting Blindness that is formed for the purpose of this award.

(s) **Milestones** shall have the meaning set forth in Exhibit B.

(t) **Milestone Award Accounting** shall mean a detail of all expenditures of the Award Funds expended to achieve each milestone.

(u) **Milestone Reports** shall mean a scientific progress report to be submitted in an electronic format, which includes a detailed summary of the work accomplished in achieving each milestone of the Award Term in the form attached hereto as Exhibit D and an updated budget, in the form attached hereto as Exhibit F or as amended from time to time by the Gund-Harrington Initiative. The Gund-Harrington Initiative will supply the most current form of Milestone Report template in electronic form as needed.

(v) **New Institution** shall have the meaning set forth in Section 11(a).

(w) **Patent Policy** shall mean FFB's patent policy, attached hereto as Exhibit E.

(x) **Principal Investigator** shall have the meaning set forth in the preamble to this Award Agreement.

(y) **Related Materials** shall mean elements and materials related to an Invention, including, but not limited to the working papers, notes, data, methods, procedures, and biological materials

if for any reason such element or material is not deemed to be Award Research or an Invention.

(z) **Relocation Request** shall have the meaning set forth in Section 11 and contain all elements of a Final Report and a Final Award Accounting.

(aa) **Reports** shall mean the reports required to be submitted to the Gund-Harrington Initiative under this Agreement.

(bb) **Representative** shall have the meaning set forth in Section 19(c).

(cc) **Significant Equipment** shall mean the equipment purchased with Award Funds, costing at least$5,000 per unit and having a useful life of at least two years.

(dd) **Sponsoring Institution** shall have the meaning set forth in the preamble of this Award Agreement.

(ee) **Upfront Award Payment** shall mean that part of the Agreed Budget, not to exceed ten percent (10%) of the total budget that will be paid within thirty (30) days of the date on which this Award Agreement is fully executed.

2. Commencement. This Agreement shall be executed within thirty (30) days after its receipt. Awardee shall commence Award Research within a reasonable time following the execution of this Award Agreement and Award Research shall be conducted materially in accordance with the research as described in the Application. The Gund-Harrington Initiative may terminate this Award Agreement in accordance with Section 6 or 20 or otherwise in accordance with this Agreement and/or may require the Principal Investigator to resubmit a award application for consideration with new award applications the following year.

3. Award Funds.

(a) **Use of Award Funds.** All Award Funds shall be used exclusively for the purposes specified in the
Application and in strict compliance with the Approved Budget, and shall not be used for any portion of the Award Research other than as specifically set forth in the Approved Budget. Approved Budget Award Funds cannot duplicate funds from any other sources. However, Award Funds may supplement support from other sources.

(b) **Distribution of Award Funds.**

(i) Upfront Award Payment shall be distributed within thirty (30) days after the date on which this
Award Agreement is fully executed. Subsequent award payments shall be distributed upon completion of each of the agreed milestones in accordance with the Approved Budget. However, continued funding is conditional on your meeting certain obligations and deliverables including timely submission of expense and progress reports, participation in an annual GHI-TRAP Symposium and participation in an annual HDI Scientific Symposium. Multi-year support is not automatic and is dependent upon progress reports being favorably reviewed by the Gund-Harrington Initiative, milestones being judged to have been met, and a favorable determination of the quality of the scientific research performed, and its continued high relevance to the Gund-Harrington Initiative. Failure to achieve milestones may lead to premature termination of this Agreement.

(ii) *Gund-Harrington Initiative's Response.* The Gund-Harrington Initiative shall, in its sole discretion, take one of the following steps within thirty (30) days after its receipt of the

Award milestone Reports required pursuant to this Agreement:

(A) distribute to the Principal Investigator the Award payment agreed for that milestone;

(B) provide written notice describing any deficiency or unsatisfied Milestones and permit the
Sponsoring Institution and Principal Investigator thirty (30) days to cure the deficiency or satisfy the applicable Milestones to the satisfaction of the Gund-Harrington Initiative (or additional time to cure, provided that such additional time is in writing); or,

(C) provide written notice that this Award Agreement has been terminated by the Gund-Harrington Initiative.

4. <u>Collaboration with ISC.</u>

Collaboration between the applicant and the ISC is a requirement of this award. Failure of the applicant to accept the guidance of the ISC may be the basis for the termination of this award. Pursuant to the Grant agreement Gund-Harrington Scholars will, at the start of funding, meet with the members of the HDI ISC to define and agree upon a development-oriented, milestone-based program and budget. Specifically, direct funding support will be milestone-driven, contingent on development progress and ongoing engagement with the ISC. Either FFB or HDI may provide additional direct support during the course of the project, at their discretion. Follow on funding by HDI will require that Gund-Harrington Scholars follow HDI procedures, including formal recommendation by the ISC and approval of the Harrington Project Investment Advisory Board (the "IAB") consistent with the Grant agreement.

Through the duration of the Grant agreement, HDI will provide the Center awardees with the following:

- Access to ISC-supported consultants with significant industry experience
- A person or team from the ISC assigned to each awardee to provide active project guidance/management
- Analysis of IP strategy
- Commercial and Market assessment
- Consideration for supplementary HDI/ISC funds, subject to an additional signed written agreement between the parties and a Gund-Harrington Scholar's institution.
- Facilitated access to strategic investment and commercial partners for future development

ISC support also includes facilitated access to an ISC/institutional consortium and resources including Contract Research Organizations ("CROs") and academic drug discovery centers that can provide:

- High throughput screening ("HTS") including screen development
- Medicinal chemistry
- Preclinical development including toxicology, safety pharmacology, and Drug Metabolism and Pharmacokinetics ("DMPK")
- Pharmaceutical development including formulation

5. Reports. Awardee is required to submit the Reports to the Gund-Harrington Initiative as set forth below. Submission of Reports and their approval by the Gund-Harrington Initiative are necessary conditions for further funding under this Award. The following reports are required:

(a) **Milestone Reports.** Upon completion of a Milestone a **Milestone Scientific Report** and a **Milestone Financial Report** (expenses incurred on Exhibit F) are required, along with a request for the Milestone payment. Scientific Milestone reports are required within fourteen (14) days of completing the experiment(s) associated with the Milestone. Reporting of outcomes to the Gund-Harrington Initiative cannot be postponed while waiting for publication.

(b) **Summary Progress Reports.** Summary Progress Reports may also be requested from time to time to help the Gund-Harrington Initiative in its assessments and to meet other operational needs of the Foundation Fighting Blindness and the Harrington Discovery Institute. These must be provided promptly when requested.

(c) **Final Reports.** Within thirty (30) days after the Grant end date, Awardee shall submit the following final reports: (i) A final scientific narrative progress report summarizing all the data generated during the Award Research, the activities supported by the Award, the successes or difficulties the Awardee had in achieving its goals, not exceeding ten (10) pages (the "Final Report"); and (ii) a financial expenditure report itemizing all expenses incurred during the entire Award period. Awardee acknowledges and agrees that Report shall be treated as Awardee Confidential Information. The obligation to provide the above Reports shall survive termination of this Award Agreement and any part of which was funded by Award Funds.

(d) **Maintaining Contact.** In addition to written Reports specified in this Agreement, the Gund-Harrington Initiative will expect award recipients to remain in close contact with the ISC assigned to the award.

6. No-Cost Extension ("NCE"). If Awardee wishes to use any unexpended Award Funds to continue work on the Award Research, the Awardee may request no less than four (4) weeks before the expiration of the Award an extension of the Award term to expend remaining funds. The Awardee shall submit such request to the Gund-Harrington Initiative for review, which request shall include a specific description of what portion of the Award Research is to be funded by such unexpended Award Funds. The acceptance of the NCE will be at the discretion of the Gund-Harrington Initiative.

7. Termination by Parties. Either the Gund-Harrington Initiative or the Awardee may terminate this Award Agreement upon thirty (30) days prior written notice to the other. Upon any such termination, the Awardee will submit a Final Report (per Section 4) and return any unused funds to the Gund-Harrington Initiative, and the Gund-Harrington Initiative and Awardee shall have no further obligations to each other except as specifically set forth in this Award Agreement. Except in the event of termination of this Award Agreement by the FFB for cause, all non-cancelable commitments pertaining to the Award Research that were made by Award Awardee in good faith prior to Awardee's receipt of the notice to terminate this Award Agreement will be paid, except that such commitments plus Award Funds previously distributed shall not exceed the Award.

8. **Change of Scope.** Awardee must provide the Gund-Harrington Initiative with written request and justification of any material changes in the purpose, structure, character, operation, or governance of the Award Research. All such changes to the supported activities must be approved in writing by the Gund-Harrington Initiative prior to implementation.

9. **Accounting.** Awardee will maintain a separate accounting for the Award Funds.

10. **Budget Modification.** The Principal Investigator does not need approval from the Gund-Harrington Initiative for budget modifications that reallocate money between line items in the Approved Budget, except that Awardee must obtain the Gund-Harrington Initiative's approval for any changes in the travel budget, or adjustments of the Principal Investigator salary allocation by more than twenty percent (20%). Approval of such a request is in the sole discretion of the Gund-Harrington Initiative and must be received in writing from the Gund-Harrington Initiative prior to implementation.

11. **Participation in other Award Research.** During the Award Term, the Principal Investigator shall pursue the Award Research diligently throughout the Award Term and agrees not to participate in any agreement or activity that would prohibit the disclosure of the Principal Investigator's research or otherwise impair the Principal Investigator's ability to pursue the Award Research diligently or to otherwise satisfy the terms of this Award Agreement, unless the Principal Investigator obtains prior approval in writing from the Gund-Harrington Initiative.

12. **Relocations.**

(a) **Request to Relocate.** If the Principal Investigator wishes to relocate to another institution (hereinafter the **"New Institution"**) during the Award Term, continuation of the Gund-Harrington Initiative funding is subject to the prior written approval of the Gund-Harrington Initiative after the Principal Investigator and Sponsoring Institution submit in writing a Relocation Request. The Gund-Harrington Initiative shall not consider any relocation request unless the Principal Investigator and Sponsoring Institution meet the following requirements.

The Principal Investigator must:

(i) *Relocation Requests.* Provide the Gund-Harrington Initiative a written request for such relocation (a **"Relocation Request"**) at least thirty (30) days prior to such relocation and,

(ii) *Inventions and Relocation Progress Report.* Within ten (10) days after making such relocation request, the Principal Investigator shall:

(A) furnish to the Gund-Harrington Initiative a list of all Inventions as of such date, and

(B) furnish to the Gund-Harrington Initiative a Relocation Progress Report, to include current status of the Award Research and the feasibility of continuation of the Award Research at the new institution and proof of application for IRB and IRC approval at new institute as appropriate.

(iii) All the above listed documents shall be certified as accurate and complete by signature on a transmittal cover letter from both the Principal Investigator and the Sponsoring Institution.

(b) **Review of Relocation Requests.** The Gund-Harrington Initiative shall, at its sole election, have the right to approve the Relocation Request, terminate this Award Agreement, or allow the Sponsoring Institution to select a new Principal Investigator, who shall be subject to the Gund-Harrington Initiative's prior approval. If Gund-Harrington Initiative approves the Relocation Request, any Significant Equipment and any human tissue samples or extracts and transgenic mice used in the

research shall be transferred to the New Institution.

(c) **Cooperation between Sponsoring and New Institution.** Sponsoring Institution agrees that if the Relocation Request is approved, it will cooperate with the New Institution in order to timely commercially exploit Sponsoring Institution's Inventions, where Sponsoring Institution's consent is required for such commercialization or production of any Invention owned by the New Institution.

(d) **Obligations of New Institution.** New Institution shall execute a counterpart of this Award Agreement agreeing to be bound by all the terms and provisions hereof applicable to or binding upon Sponsoring Institution from and after the date of New Institution's execution of such counterpart of this Award Agreement.

13. Intellectual Property and Inventions. Developing and disposition of property relating to the Award shall be as specified in FFB Patent Policy attached to this Award Agreement as Exhibit E. The terms and provisions of the Patent Policy shall survive termination of this Award Agreement.

14. Compliance with Applicable Law. The Sponsoring Institution and its personnel, agents and employees hereby agree to abide by all applicable state, federal, and foreign law, and any rules, regulations and guidelines promulgated thereunder, with respect to or which otherwise relate to or are applicable to their performance hereunder or that may affect the Award Research (hereinafter referred to as **"Applicable Law"**). Such Applicable Law includes the non-infringement of patent or other intellectual property rights of any third party in connection with the performance of the obligations under this Award Agreement.

15. Human Subject Research.

(a) **Human Subject Research.** The Principal Investigator must comply with all Applicable Law related to human subject research, including National Institutes of Health guidelines and obtain written approval from the Sponsoring Institution's IRB before undertaking any form of human subject research.

Informed Consent. If any informed consent form contains a waiver or release of claims by the human subject in favor of any party, the Sponsoring Institution shall cause such waiver or release to apply to claims against FFB and the University Hospitals Health System, Inc., d/b/a Harrington Discovery Institute

(b) to the full extent it applies to such other party or parties.

(c) **Waiver of Consent.** If the Sponsoring Institution requests a waiver of the consent and/or authorization requirement, as set forth in Applicable Law from the IRB, no Award Research may be conducted pursuant thereto until the IRB has issued appropriate documentation of such waiver in accordance with Applicable Law.

(d) **No Gund-Harrington Initiative Responsibility.** Human subjects studied in the course of research conducted pursuant to the Award Research are under no circumstances a responsibility of the FFB and the University Hospitals Health System, Inc., d/b/a Harrington Discovery Institute and Awardee hereby releases FFB and the University Hospitals Health System, Inc., d/b/a Harrington Discovery Institute from any liability therefor or obligations with respect thereto.

(e) **Delay Due to Lack of Consent or Approval.** Sponsoring Institution shall promptly notify the Gund-Harrington Initiative if the process of obtaining an approval or consent will require thirty (30) days or more.

(f) **No Additional Authority.** Nothing in this Section awards Awardee the right to use the

Award Funds for any purpose other than as set forth in the Approved Budget. By way of example and not limitation, this Section does not allow Award Funds to be used for human subject research, tests or studies, except to the extent (if any) specifically set forth in the Approved Budget.

16. Treatment of Animals. Animal care and use for any Award Research will be carried out in accordance with Applicable Law, including national or international guidelines for animal care and use. In the U.S., this includes the Animal Welfare Act, implementing U.S. Department of Agriculture regulations, the U.S. Public Health Service Policy on Humane Care and Use of Laboratory Animals, National Institutes of Health (including the Office of Laboratory Welfare) compliance materials, and the Institutional Animal Use and Care Committee. Sponsoring Institution shall provide proof of appropriate accreditation, or its equivalent, upon request by FFB. Nothing in this Section awards Awardee the right to use the Award Funds for any purpose other than as set forth in the Approved Budget. By way of example and not limitation, this Section does not allow Award Funds to be used for animal research, tests or studies, except to the extent (if any) specifically set forth in the Approved Budget.

17. Indemnification.

(a) **Gund-Harrington Initiative - FFB.** In recognition of the fact that the only activity in which the FFB is engaged with respect to this Gund-Harrington Initiative Award Agreement is the payment of the Award Funds, the parties acknowledge and agree that in entering into this Award Agreement FFB assumes no responsibility for any of the activities of the Principal Investigator and/or Sponsoring Institution Award Funds in accordance with the terms set forth herein.

(b) **Gund-Harrington Initiative - HDI:** In recognition of the fact that awards are funded after the recommendations of the Harrington Discovery Institute review panel and Scientific Advisory Board, the Harrington Discovery Institute review panel and its Scientific Advisory Board members do not assume responsibility for the conduct of the project or the acts of the Principal Investigator, since both are under the direction and control of the Principal Investigator's institution and are subject to the institution's medical and scientific policies.

(c) **Sponsoring Institution.** In recognition of the research activities by Awardee, which could possibly result in bodily injury or injury to property, it is further agreed that as between the Gund-Harrington Initiative on the one hand, and Awardee on the other, Sponsoring Institution assumes any and all risks of personal injury and property damage attributable to the negligent acts or omissions of the Sponsoring Institution and the officers, employees, servants and agents thereof while acting in the scope of their employment by Sponsoring Institution related to the Award Research. To the fullest extent it is legally permitted to do so, the Sponsoring Institution shall hold harmless the Gund-Harrington Initiative and its officers, directors, employees, scientific advisors, independent contractors and agents and defend and indemnify them from any claims, damages, liabilities, losses, costs or expenses (including, but not limited to reasonable attorney's fees) that may arise as a result of or in any way relating to claims, demands, or judgments against them arising out of or in any way related to any act, error, omission, negligence, willful misconduct or any activities carried out in connection with this Award Agreement by the Principal Investigator and/or the Sponsoring Institution, and/or any person(s) acting under the supervision, direction or control of the Principal Investigator and/or the Sponsoring Institution, except to the extent caused solely by the negligent acts or omissions of the Gund-Harrington Initiative with no negligence on the part of Award Awardee. Sponsoring Institution's obligations under this Section 11(b) shall survive termination of this Award Agreement.

18. Insurance. Sponsoring Institution, at its sole cost and expense at all times during Award Term, shall maintain in full force and effect insurance covering the foreseeable risks associated with the Award Research (including damages to persons or property) and shall provide the Gund-Harrington Initiative with evidence thereof.

19. Publicity, Exhibits and Publication.

(a) **Announcement and Gund-Harrington Initiative Publication of Award.** The Sponsoring Institution and Principal Investigator will cooperate with the Gund-Harrington Initiative in announcing the award of this Award. Such cooperation shall include submission of an abstract of the Award Research to be conducted with the Award that can be publically disclosed at the time the award is announced. The Sponsoring Institution and Principal Investigator shall cooperate with the Gund-Harrington Initiative in connection with any written, photographic, filmed, broadcast or other forms of materials the Gund-Harrington Initiative elects to produce to publicize the work.

(i) **Cooperation with Donors to FFB.** If a donor to FFB provides financial support to this Award, the Principal Investigator agrees to participate in reasonable publicity efforts on behalf of such donor if requested by such donor or FFB and that FFB may share Reports with such donor

(ii) **Prior Notification of Promotion, Presentation or Exhibition.** The Sponsoring Institution and Principal Investigator shall give the Gund-Harrington Initiative written notice at least thirty (30) days prior to any advertising, promotion, publication, exhibition or presentation relating to Award Information (which notification shall include a copy of the materials intended for release, as well as the details of the information to be disclosed and the time, place and manner of such disclosure).

(iii) **Right to Publish.** The Sponsoring Institution and the Principal Investigator shall have the right to publish, present or otherwise disclose Award Information, subject to the following:

(A) *Gund-Harrington Initiative Review for Possible Patentable Subject Matter.* The Principal Investigator will provide the Gund-Harrington Initiative advance copies of any Award Information submitted for publication, exhibit or presentation during the Award Term in accordance with (ii) above, and the Gund-Harrington Initiative may require that the Principal Investigator delay publishing, exhibiting or presenting Award Information if there is patentable subject matter present.

(B) *Credits.* All published works (including on-line publications), exhibitions, presentations or other disclosures of Award Information or summaries thereof by Sponsoring Institution or Principal Investigator must display the designation, "Supported by a Research Award from Gund-Harrington National Initiative for Fighting Blindness, a collaboration between the Foundation Fighting Blindness (FFB) and Harrington Discovery Institute (HDI)."

(b) **FFB Website.** FFB shall have the right to include published Award Information results on its website or in other FFB materials. The Principal Investigator (or other research personnel designated by the Sponsoring Institution) shall have the right to review FFB's proposed website content solely for scientific accuracy and shall furnish any comments to FFB in writing within ten (10) business days of his/her receipt of such proposed web content.

(c) HDI Website. HDI shall have the right to include published Award Information results on its website or in other HDI materials. The Principal Investigator (or other research personnel designated by the Sponsoring Institution) shall have the right to review HDI's proposed website content solely for scientific accuracy and shall furnish any comments to HDI in writing within ten (10) business days of his/her receipt of such proposed web content.

20. Confidentiality.

(a) **Confidential Information, General.** Except as expressly set forth elsewhere in this Award Agreement, all information furnished by any party to this Award Agreement or its Representatives (as defined in Subsection (c) below) to any other party to this Award Agreement that is designated as **"Confidential"** at the time of its disclosure shall be, except as otherwise provided herein, considered confidential and proprietary to the disclosing party **("Confidential Information")** and shall be kept strictly confidential by the receiving party and shall not be used by the receiving party or disclosed by the receiving party or any Representative (as such term is defined in Subsection (c) below) without the prior written consent of the disclosing party unless otherwise permitted by this Award Agreement.

(b) **Confidential Information shall not include:** the Award Research or information which (1) is or becomes generally available to the public other than as a result of the unauthorized disclosure by the receiving party; (2) is or becomes available to the receiving party on a non-confidential basis from a source other than the disclosing party (or its Representatives), provided that such source is not prohibited from disclosing such information to the receiving party by a contractual, legal or fiduciary obligation to the disclosing party (or its Representatives); (3) is independently developed by the receiving party prior to disclosure to it by the disclosing party (or its Representatives); or (4) is required by law to be disclosed.

(c) **Representative.** As used in this Section, the term **"Representative"** shall include any agent or representative of the applicable party, and shall be broadly interpreted to include, without limitation, any affiliate, director, officer, member, manager, partner, employee, agent or advisor of such party or of such party's affiliate and consultants who agree in writing to like terms of confidentiality.

(d) **Legal Requests to Disclose.** If pursuant to Applicable Law the receiving party or its Representative is requested or required to disclose any Confidential Information, the receiving party or its Representative will use reasonable efforts to provide the disclosing party with notice of such request(s) or requirement(s) to enable the disclosing party to seek an appropriate protective order or other appropriate remedy and/or waive compliance with the provisions of this Award Agreement.

(e) **Destruction of Confidential Information.** Upon request of the disclosing party, the receiving party or its Representative shall promptly deliver to the disclosing party or destroy all Confidential Information in tangible form (including, without limitation, all writings, notes, memoranda, papers, drawings, specifications, programs, digital data or other materials) supplied to the receiving party or its Representatives pursuant to this Award Agreement and shall not retain any copies or other reproductions of such materials in whole or in part, in any form or on any medium whatsoever, including without limitation, on any computer hard drive, server or network, except to the extent necessary to comply with legal and audit requirements.

(f) **Period of Confidentiality.** The receiving party shall keep confidential and shall not disclose Confidential Information for a period of two (2) years from the date of termination of this Award Agreement.

21. Breach; Termination.

(a) **Material Breach.** The failure of the Awardee to adhere to any of the terms and conditions set forth in this Award Agreement shall constitute a material breach of this Award Agreement. In the event of a material breach of this Award Agreement by the Awardee, the Gund-Harrington Initiative shall give Awardee written notice specifying the nature of the breach and, if curable, Awardee shall have sixty (60) days from its receipt of such notice to cure such breach. If such breach is not curable or, if curable, Awardee has not cured or has not taken steps in a good faith effort to cure within the aforesaid period, (1) the Gund-Harrington Initiative may terminate this Award Agreement immediately upon written notice to Awardee, or may, at its discretion, attempt to continue to resolve such breaches, provided that any such election to continue attempting to resolve such breach shall not prejudice the Gund-Harrington Initiative's ongoing right to terminate this Agreement, and (2) the Gund-Harrington Initiative shall be entitled to pursue all remedies to which it is entitled at law or in equity as a result of such material breach, which remedies may include injunctive or similar relief for material breaches for which monetary damages are inapplicable, inadequate or insufficient. No election by the Gund-Harrington Initiative to pursue less than all of the remedies to which it is entitled shall be considered an election or waiver of remedies.

(b) **Events Occurring Upon Termination under Certain Provisions.** In the event this Award Agreement is terminated by the Gund-Harrington Initiative:

(i) *Final Report, Final Award Accounting, Unexpended Funds.* The Principal Investigator shall submit a Final Report, Final Award Accounting and reimburse unexpended funds within thirty (30) days after the termination of this Award Agreement;

(ii) *Inventions.* FFB's rights with respect to the Inventions shall be governed by the terms of Exhibit E; and,

(iii) *Significant Equipment.* Significant Equipment purchased with Award Funds shall be transferred to FFB or its designee at FFB's sole election.

22. Dispute Resolution. In the event of any dispute between the Gund-Harrington Initiative and Awardee with respect to any subject matter covered under this Award Agreement, either Awardee or the Gund-Harrington Initiative may serve notice to the other specifying the nature of such dispute in reasonable detail. As soon as practicable after receipt of such notice, one (1) representative from each of Awardee and the Gund-Harrington Initiative shall meet at a mutually agreed upon time and location for the purpose of resolving such dispute. The parties shall engage in good faith discussions and/or negotiations for a period of up to thirty (30) days to resolve the dispute. In the event any dispute is not resolved by the parties, then either Awardee or the Gund-Harrington Initiative may decide to institute arbitration proceedings by providing written notice to that effect to the other, and the parties shall resolve such dispute by final and binding arbitration, according to the then-current rules of the American Arbitration Association (**"AAA"**). The arbitration will be conducted by one (1) arbitrator who shall be reasonably acceptable to the parties and who shall otherwise be appointed in accordance with AAA rules. Any arbitrator chosen hereunder shall have educational training and industry experience sufficient to demonstrate a reasonable level of scientific, financial, medical, and biotechnology industry knowledge.

23. Other Terms and Conditions.

(a) Sponsoring Institution hereby represents and warrants that it is an educational institution exempt from federal income tax under the Internal Revenue Code (IRC) Section 115(1). Sponsoring Institution agrees to inform FFB immediately of any actual or threatened change in its tax exempt status.

(b) Awardee shall inform the Gund-Harrington Initiative immediately of any institutional or staffing changes that may adversely affect the implementation of the funded activities and services under this Award Agreement or that may adversely affect the reputation of the Awardee or the FFB's.

(c) By accepting this Award and entering into this Award Agreement, the Awardee agrees to use the Award Funding solely for the scientific research contemplated by this Award Agreement as described in the Application.

(d) Sponsoring Institution represents and warrants that as of the date of this letter and throughout the term of this Award Agreement, Sponsoring Institution is duly registered and in good standing as a non-profit educational institution in the state in which Sponsoring Institution is incorporated and/or is conducting its principal business.

(e) Sponsoring Institution represents and warrants that it is not debarred by a competent health authority (including, if applicable, the U.S. Food and Drug Administration (**"U.S. FDA"**)) or by the Professional Council of Physicians; Sponsoring Institution shall not employ, contract with or retain any person directly or indirectly to perform work under the Agreement if such a person is or becomes debarred by a competent health authority (including, if applicable, the U.S. FDA) or by the Professional Council of Physicians. Upon written request from FFB, Sponsoring Institution shall, within ten (10) calendar days, provide written confirmation that it has complied with the foregoing obligation.

24. Notice. Any notices or requests to be given hereunder to a party shall be made via U.S. Mail, return receipt requested, or express courier to such party's address given below or to the e-mail address given below.

If to Award Recipient:
<FIRST, INITIAL, LAST, DEGREE>
<ADDRESS>

If to Sponsoring Institution:
<NAME OF INSTITUTION>
<ADDRESS>
Attn: <INSTITUTION OFFICIAL>

If to Gund-Harrington Initiative:
C/o Foundation Fighting Blindness
7168 Columbia Gateway Drive
Suite 100
Columbia, MD 21046-3256
Attn: Director, Grants and Award Program

25. No Third-Party Beneficiaries or Assignment. This Award Agreement shall not in any manner whatsoever confer any rights upon or increase the rights of any individual or organization not a party to this Award Agreement. This Award Agreement may not be assigned by the Sponsoring Institution or the Principal Investigator without the prior written consent of the Gund-Harrington Initiative.

26. Entire Agreement; Modification. This Award Agreement, including all exhibits attached hereto, constitutes the entire agreement between the parties concerning the subject matter herein, and all prior agreements, representations, discussions, promises and negotiations are superseded and merged herein. No waiver, amendment or modification hereof shall be effective unless in writing signed by a duly authorized representative of each party.

27. Survival of Terms. The following terms and provisions of this Award Agreement shall survive termination of this Award Agreement: (1) any Section or subsection that by its terms expressly survives termination of this Award Agreement and any other term or provision of this Agreement that effectuates or otherwise reasonably relates to or must be considered or construed in connection with application or effect of any such Section or as the context may otherwise clearly require, (2) the application of Exhibit E, and (3) without duplication, Sections 4 (with respect to Final Reports), 6, 12, 16, 17, 19, 20, 21, and 26.

28. Electronic Signature. The parties agree that this Award Agreement may be executed and delivered by facsimile, electronic mail, internet, or any other suitable electronic means, and the parties agree that signatures delivered by any of the aforementioned means shall be deemed to be original, valid, and binding upon the parties, and that this Award Agreement may be executed in counterparts, with each such counterpart in the aggregate constituting one Award Agreement.

[Remainder of this page is blank. Signatures contained on following page.]

SIGNATURES

THE PARTIES HERETO hereby execute this Award Agreement effective as of the date first listed above.

University Hospitals Health System, Inc.,
d/b/a Harrington Discovery Institute

By: _____
Name: _____
Title: _____
Date: _____

FFB:

FOUNDATION FIGHTING BLINDNESS

By: _____
Name: William Schmidt
Title: Chief Executive Officer
Date: _____

SPONSORING INSTITUTION:

<INSTITUTION>

By: _____
Name:_____
Title:_____
Date: _____

PRINCIPAL INVESTIGATOR:
(Read and Acknowledged)

<NAME>

Signature: _____
Institution:
Date: _____

EXHIBIT A

AWARD APPLICATION
(Append the complete application with budget)

EXHIBIT B

APPROVED MILESTONES AND PAYMENTS FOR THE GHI SCHOLAR AWARD

On this and continuing pages, as necessary, itemize the final, Gund-Harrington Initiative approved agreement for:

- *each milestone(add additional sections as needed)*
- *the criteria by which each milestone is to be assessed*
- *the agreed milestone payment upon successful completion, as determined by the Gund-Harrington Initiative*

MILESTONES AND PAYMENTS

Milestones, Payments, and Assessment Criteria

Milestone 1: DESCRIPTION (Duration in months)
[Start Date-End Date]
Cost:

Evaluation Criteria and Deliverables:

Milestone 2: DESCRIPTION (Duration in months)
[Start Date-End Date]
Cost:

Evaluation Criteria and Deliverables:

Milestone 3: DESCRIPTION (Duration in months)
[Start Date-End Date]
Cost:

Evaluation Criteria and Deliverables:

Milestone 4: DESCRIPTION (Duration in months)
[Start Date-End Date]
Cost:

Evaluation Criteria and Deliverables:

Milestone 5: DESCRIPTION (Duration in months)
[Start Date-End Date]
Cost:

Evaluation Criteria and Deliverables:

EXHIBIT C

TEMPLATE FOR
SCIENTIFIC PROGRESS REPORTS AND FINAL REPORT

Principal Investigator's Name (Last, First):
Title of Research Award Research:
Gund-Harrington Initiative Award Number:
Award Year and Program Name:

I. Overview
Brief summary of original award research goals/aims (recommended limit 1 page)

II. Conclusions
Brief non-technical summary of conclusions (recommended limit 3 paragraphs)

> *This summary must be written in a way that it may be provided directly to a lay and clearly addresses the questions: how has this accelerated the field towards the clinic or, put more colloquially – what was the bang for the buck.*

III. Scientific Progress
Detailed summary of work accomplished during the complete award period as related to the original award research goals and milestones (recommended limit <10 pages)
Provide supporting information for any deviations from a goal or milestone that significantly impacted the project scope or timeline.
If timeline impacts have occurred, provide a modified milestone Gantt chart/timeline, indicating where these modifications have occurred.
Supporting Material (i.e. Figures, Tables, References)
Percent Completion Relative to the Timeline for Each Goal/Aim

IV. Appendix
Detailed report of expenditures for the period covered by the report (recommended limit 2 pages) (Exhibit F)
Products/outcomes during this reporting period (including publications)

EXHIBIT D

MILESTONE REPORT TEMPLATE

Principal Investigator's Name (Last, First):
Title of Research Project:
Gund-Harrington Initiative Award Number:
Award Year and Program Name:

I. Overview
Brief summary of original award research goals and milestones (recommended limit 1 page)

II. Conclusions
Brief non-technical summary of conclusions (recommended limit 3 paragraphs)

> *This summary must be written in a way that it may be provided directly to a lay and clearly addresses the questions: how has this accelerated the field towards the clinic or, put more colloquially – what was the bang for the buck. This summary may be used in the assessment of continued funding.*

III. Scientific Progress
Detailed summary of work accomplished, for each milestone completed, describe:

- *the agreed milestone*
- *the agreed assessment criteria for the milestone*
- *the work completed*
- *the results*
- *the justification for how each criterion for judging the milestone has been met successfully*

(recommended limit <10 pages)

IV. Proposed Studies for Remainder of Award
Describe the next milestone, the work you intend to do, and any changes to the originally agreed project with rationale (recommended limit 2 pages).
Supporting Material (i.e. Figures, Tables, References)
Percent completion relative to the timeline for each goal/aim

V. Appendix
Detailed report of expenditures (recommended limit 2 pages) (Exhibit F)
Detailed budget for remainder of award term
Products/outcomes during this reporting period (including publications)

EXHIBIT F

FINAL Gund-Harrington Initiative APPROVED AWARD BUDGET

Instructions to complete Budget using the embedded Excel Template (next page):

- *Activate the Excel version of the template by double clicking anywhere within the table*
- *Complete the budget with the requested information.*
- *When possible use formulas (e.g. SUM) for totals.*
- *Insert additional rows if necessary*
- *You can return to the Word version at any time by clicking outside of the excel box*
- *The document can be saved at anytime in either Word or Excel versions*
- *Only the completed EXCEL version should be submitted with the award application.*

Budget Category						
Personnel						
(Name, Degree, & Title)						
(Salary + Fringe; % Effort)						
Total Personnel						
Supplies (Itemize)						
Total Supplies						
Patient Costs (Itemize)						
Total Patient Costs						
Animal Costs (Itemize)						
Total Animal Costs						
Travel Cost (Itemize)						
FFB TRAP Travel (3 Trips)	N/A	N/A	N/A	N/A	N/A	$ 4,500
Other Travel (# Trips)	N/A	N/A	N/A	N/A	N/A	
Total Travel Costs						
Other Costs (Itemize)						
Total Other Costs						
TOTAL						

EXHIBIT E

GHI Scholar Award of
THE FOUNDATION FIGHTING BLINDNESS
PATENT POLICY

Whereas, The Foundation Fighting Blindness ("FFB") is a not-for-profit organization supported by public contributions; and

Whereas, FFB, since its inception in 1971, has used these public contributions to fund scientific research into the causes of and potential cures for retinitis pigmentosa, Usher syndrome, macular degeneration and allied retinal diseases; and

Whereas, FFB has a broad network and deep domain expertise in inherited retinal diseases; and

Whereas FFB has formed a collaboration with the Harrington Discovery Institute to create The Gund-Harrington National Initiative for Fighting Blindness to provide financial and drug development resources to specifically facilitate bridging the recognized gaps (“Valley of Death”) in the translation of laboratory-based translational research to a commercially viable, pharmaceutically acceptable lead product with the specific intent of commercializing the therapy for the benefit of patients with retinal diseases; and

Whereas, FFB believes that it has a responsibility to adopt policies that will foster Inventions (as defined in Section 8 of this Exhibit E) and progress toward making such Inventions available to the public;

Therefore, FFB hereby adopts the following patent policy (this "Patent Policy").

1. This Patent Policy shall be adhered to by, and is binding on, all individuals accepting funding for research from FFB and, to the extent such individuals are employed by a university or other institution, is also binding on such university or institution (collectively "Awardees" and individually "Awardee"). Awardees shall be responsible for ensuring agreement to the terms and conditions of this Patent Policy by any subcontractors of Awardee receiving FFB funding through Awardees. The terms and conditions of this Patent Policy will be appended to any FFB award agreement (“FFB Award”) and will be deemed accepted by Awardees upon acceptance of an FFB Award.

2. Except as provided in Section 3 below, this Patent Policy shall govern the relationship between FFB and each Awardee with respect to any Inventions made while conducting research pursuant to an FFB Award, as follows:

(a) Procedures for Notification of Invention(s). The Awardee shall promptly notify in writing the Director, Early Translational Research Program for FFB as soon as practicable after any Invention(s) by Awardee, or by any person working under the supervision and direction of Awardee.

(b) Election to Pursue Intellectual Property Protection for Invention(s).

(i) Awardee may elect, at Awardee's sole discretion, to pursue patent protection, copyright registrations or other intellectual property registrations or protection (collectively, "IP Registrations") for any Invention(s).

(ii) Awardee agrees to notify FFB within a reasonable period of time, not to exceed one hundred eighty (180) days after the disclosure of an Invention(s) to FFB, of Awardee's election to pursue, or not to pursue, IP Registration(s) for any such Invention.

(iii) If Awardee elects to pursue IP Registration, Awardee further agrees, as soon as practicable thereafter, to file an application on such Invention(s) with the United States Patent and Trademark Office, United States Copyright Office, or a similar foreign office, as applicable, and agrees to provide confirmation of such filing to FFB’s Science Department in writing within sixty (60) days after filing.

(iv) Thereafter, Awardee agrees:

- to notify FFB in writing within sixty (60) days after either the issuance of an IP Registration or a final confirmation or determination that such IP Registration will not issue, and
- to send a signed hard copy of any applicable maintenance fee and/or other fee-related schedule(s) to FFB.

(c) Abandonment of, or Election not to Pursue, IP Registration for an Invention(s).

If Awardee elects not to pursue an IP Registration for any Invention or to abandon an application for an Invention, then Awardee agrees to award to FFB an exclusive, sublicensable license that would: (i) provide FFB the right to assume the responsibilities, the management and commercialization of any such Invention; and (ii) accord Awardee a refund of its out-of-pocket IP costs relating to the Invention upon the sublicensing of the Invention to a third party, or commercialization of a product based on the Invention. Awardee shall protect the confidentiality of any such Invention so that FFB's rights to seek IP Registration are preserved.

(d) Obligation to License Invention(s) for Use in Practical Applications. Awardee agrees to take all reasonable steps necessary to award a royalty-bearing license(s) under the Invention(s) and any related IP Registration(s) to a third party or parties for the purpose of bringing such Invention(s) to practical application in the field(s) of interest for which the scientific research was funded (in whole or in part) by FFB. Field herein shall mean <BRIEF DESCRIPTION OF PROJECT TO BE INSERTED HERE> and all enabling materials and methods necessary for the successful use or application of the Invention to the relevant animal models and human subjects. Awardee agrees that any such licenses so awarded to a third party shall provide that:

(i) the license award shall include an obligation on behalf of licensee to take substantial steps towards bringing such licensed Invention(s) to practical application within the field(s) of interest for which the scientific research was funded by FFB;

(ii) the Awardee will make a reasonable good faith effort to arrange a meeting between FFB and the transferee and/or licensee to discuss the licensee's intended use of the patent or copyright and related IP Registrations; and

(iii) Awardee agrees to notify FFB in writing immediately after a license under any Invention(s) and/or related IP Registration(s) has been awarded to any person or organization.

(e) Conditional, Exclusive License Award to FFB. If Awardee fails to license a third party to use and to commercialize products based upon an Invention(s) and/or IP Registration(s) related thereto for the purpose of bringing such Invention(s) to practical commercial application in the field for which the scientific research was funded by FFB before the second year anniversary of the date upon which Awardee terminates substantial work on development of the Invention (the "License Effective Date"), then Awardee agrees to award, and by acceptance of the terms of this Patent Policy does in such event hereby automatically award, to FFB an exclusive, fully paid-up right and license (the "License") effective on the License Effective Date, with the right to sublicense, under the Invention(s) and any related IP Registration(s) for the purpose of sublicensing for commercialization such Invention(s) and related IP Registration(s) solely in the specific field(s) of interest for which the scientific research was funded by FFB. If Awardee has been unable to license Inventions and/or related IP Registration(s) but can demonstrate to FFB that it is in active discussions for such license, FFB shall award a reasonable extension to Awardee, to allow it to complete such discussions. In the event the License is activated, and FFB receives any payments from the sublicensing or commercialization of the Invention(s), then Awardee and FFB agree to share such payments equally with the Awardee, except that (i) FFB shall reimburse Awardee for any out-of-pocket direct costs Awardee incurred relating to seeking or maintaining IP Registration specifically for the Invention to which FFB has the License, out of any amounts received by FFB with respect to the License; (ii) prior to dividing any amounts received with respect to the License, FFB shall be reimbursed for any amounts it expended with respect to the License after the License Effective Date; and (iii) if there are amounts applicable to (i) and (ii) above, they shall be reimbursed proportionately until fully paid.

(f) Notice of Transfer of Rights. Awardee agrees to notify FFB in writing within sixty (60) days prior to transfer of any of Awardee's right, title, or interest in or to the Invention(s) and/or related IP

Registration(s) to a third party, and agrees to negotiate to the extent possible that such transfer shall be made subject to the right of FFB to obtain the License to the transferred Invention(s) and/or related IP Registration(s) under the terms and conditions set forth in Section 2(d) and 2(e) of this Patent Policy, except that the License Effective Date specified in Section 2(e) shall be postponed until the second anniversary of the effective date of the license to a third party.

(g) Government Patent Rights**.** If any governmental funding for any research relating to the Award Research was previously or is hereafter obtained, the Sponsoring Institution shall give FFB notice thereof as soon as practicable and the Sponsoring Institution agrees to elect to retain or obtain any government patent rights arising from the governmentally funded portion of the research in accordance with the provisions of The Bayh-Dole Act, 35 U.S. C. §200 et. seq. (and/or any other Applicable Law).

3. If the patent policies of the Awardee, any institution or university by which an individual Awardee is employed, or any organizations that provided joint support for the research, conflict with this Patent Policy, it is agreed that those organizations, institutions, universities or individual Awardees and FFB shall negotiate in good faith to arrive at a mutually-acceptable resolution in conformity with FFB's policy of bringing appropriate Inventions to practical application as expeditiously as possible, provided that Awardee's acceptance of an Award from FFB shall constitute Awardee's acceptance of this Patent Policy and Awardee's representations and warranties that Awardee is not aware of any other agreement to which it is bound that conflicts with this Patent Policy at the time it accepts the FFB Award Agreement and shall not enter into any agreements after accepting an FFB Award nullifying or reducing any of FFB's rights pursuant to this Patent Policy.

4. The Awardee shall award at FFB's request up to a total of five (5) non-exclusive, fully paid up, royalty-free licenses in and to any Invention with all materials reasonably necessary to use or practice the Invention for non-commercial research purposes only, which licenses only may be transferred or sublicensed by FFB to non-profit academic institutions.

5. In addition, the Awardee, or institution or university at which an individual Awardee is employed, shall require its transferee or licensee to provide a patient assistance program to ensure that uninsured and underinsured persons have adequate access to the particular commercially sold products, services or other practical applications resulting from any Invention under this Patent Policy. In the event that a transferee or licensee determines that it would be unduly burdensome or unduly costly to provide such a patient assistance program, the transferee or licensee, as applicable, shall be required to so notify in writing FFB as promptly as possible and shall be required to negotiate in good faith with FFB to achieve a mutually-acceptable alternative arrangement.

6. If the Awardee grants any rights to the Invention(s) and/or related IP Registration(s) to a third party for commercial application and receives any amounts therefrom (whether an up-front payment, Milestone payment, royalty or equity or other amount) ("Payments"), then FFB shall receive a share of such payments determined according to the following principle: FFB shall receive a share of such Payments that will be calculated by multiplying the Payments received by the Awardee by a fraction, the numerator of which are the aggregate of FFB Awards relating to the Invention, and the denominator of which is the total direct costs incurred by the Awardee in developing the Invention, except that, neither FFB nor Awardee's share pursuant to the foregoing calculation shall be less than twenty percent (20%). The resulting amounts due to FFB shall be paid to FFB within sixty (60) days after any Payments are received by Awardee.

7. FFB reserves the right to publicize FFB's support for the Invention and to use the Awardee's name in such publicity, subject to the Awardee's right of review and approval. FFB's name and logo, however, may not be used without the prior written approval of FFB.

8. Invention Defined. "Invention" shall mean any discovery, invention, biological or chemical material or software program, whether or not patentable or copyrightable, created, conceived, or developed in whole or part as a result of FFB funding.