INNOVATIVE INVESTIGATOR RESEARCH AWARD POLICY

Administration

• The Research Department of the National Hemophilia Foundation (NHF), with counsel from scientific and lay leaders, is responsible for the administration of this award program.

• Award Recipients are not employees of NHF but of their own institution and are subject to the administrative policies and regulations of their institution.

• Only non-commercial institutions and investigators associated with a non-commercial institution are eligible for NHF grant funding.

• NHF is a nonprofit 501c3 organization and as such, grant funding is based upon fundraising efforts; therefore, all awards, grants and fellowships are contingent on available funds.

Funding

Innovative Investigator Research Award (IIRA) recipients receive funding of $60,000 a year. The IIRA can be extended for an additional 6 months. Continuation of an IIRA for an additional six months requires the submission of a continuation application and approval by the NHF Research Review Committee.

The budget has been adjusted from the initial application request to the following:

Total salary (rounded for ease of budgeting) $_____
20% fringe of requested salary (maximum) $_____
Indirect costs (8% of total award maximum) $_____
Equipment $_____
Supplies $_____
Travel $_____
Other $_____
Total $_____

Version February 2019
In consideration of the above-referenced grant ("Award") from The National Hemophilia Foundation ("NHF") and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the above-referenced Award Recipient (acting as principal) and the Institution and NHF agree to comply with the following terms and conditions. All terms not defined herein shall have the meanings assigned to them in NHF’s Awards Policies and Procedures, as may be revised from time to time, ("Policies").

1. **Acknowledgement of Policies**

The Award Recipients represent that they have read and understood NHF’s Policies, which are incorporated herein by reference and deemed an integral part of this Agreement. In the event of any conflict between the Agreement and the Policies, the terms of this Agreement shall prevail.

2. **Updates to Application Data**

The Award Recipients hereby represent that to the best of their knowledge, the information provided in their application for an NHF award (the "Application") is accurate, truthful and complete. Each Award Recipient shall notify NHF of any updates or changes to the information provided in their Application.

3. **Execution**

The Award is conditioned on NHF receiving a written acceptance of the Award on the Institution’s letterhead addressed to NHF and execution of this Research Award Agreement.

4. **Progress Report and Continuation Application**

All Award Recipients are required to submit regular scientific progress reports as per the attachment on page 13. Award Recipients intending to continue funding after the first year must also submit a continuation application as per the attached schedule. Continued funding and grant payments are dependent upon the receipt, review and approval by NHF and its Research Review Committee of scientific progress/financial reports and continuation applications as applicable, on how award monies are being utilized. (The full reporting schedule for these items can be found on page 13.)

**Final Research Report** -

A final report consisting of a summary written in lay language of the research aims accomplished, a list of any resulting articles or abstracts, and a copy of any publications must be provided within sixty (60) days after termination of the grant. This report is in addition to any interim progress report that may have been included in an application to NHF for further research support.
Financial Reports -

Award Recipients (or their institution’s contract grants representative) must submit financial reports detailing how their funding is being received and expended. Regular financial reports are due as per the attached schedule on page 13. A final progress/financial report is due within 6 weeks after termination of the grant.

5. Use of Funds

Since budgets provided in Applications are estimates of funds required to perform the research indicated, a reasonable amount of unexpended funds may remain at the end of each year and at the termination of the grant. Any unexpended funds remaining at the end of the first year may be carried over to the next six months, contingent upon approval of the recipient’s application for funding in the second year. However, all unexpended funds remaining after the termination of the grant must be returned to NHF.

Authorized Expenses -

The following expenses are, when the National Hemophilia Foundation deems them justified by the research, permitted under the institutional overhead:

1. Salary to support the awardee plus up to one additional researcher/technician to assist with the research.

2. Fringe benefits not to exceed 20% of the requested salary. Indirect costs cannot exceed 8% of the total award.

3. Equipment necessary to fulfill the project’s specific aims, not exceed $3,000 in any given year without prior approval from NHF. If purchased solely with NHF funds, equipment should reside with the project for which it is funded.

4. Supply expenses necessary to fulfill the project's specific aims, limited to 30% of the yearly award- unless a previously agreed upon exception is approved.

5. Travel expenses:
   a. Directly related to the implementation of the research;
   b. Expressly and solely for the purpose of reporting the results of NHF-supported research at suitable scientific or medical meetings;
   c. Limited to $2,000 maximum per year.

6. Costs associated with publication of the funded research.

7. Costs associated with making the products of the research (i.e., cell lines, DNA, protein, and other biological substances) available to others for research.
8. Certain patient care costs. Funds requested for hospitalization and/or professional medical services for study subjects may be granted if justification is presented in the application to show that such charges are needed for the research proposed and that the usual sources available for these costs are not adequate. All third-party payments received by the grantee institution for such services are to be used to offset the funds awarded in the grant for this purpose.

Unauthorized Expenses -

The following expenses are not permitted under NHF's IIRA program:

1. Salary or fringe benefits for anyone other than those designated in the application.
2. Salaries, travel, and/or housing related to sabbatical leaves.
3. Purchase or rental of office equipment (i.e., desktop computers, furniture, filing cabinets, or copy machines).
4. Additional indirect costs and those expenses normally covered by the indirect cost of the grantee's institution.
5. Consultant costs.
6. Fees for tuition.
7. Membership dues, subscriptions, books, or journals.

Additional Funding -

Award Recipients must submit information on all current and pending funding sources to the NHF Research Department. It is permissible for an applicant's project to receive additional funding from another source. If a “change in status” would impact a pending application, applicants are required to notify the NHF Research Department.

Record Keeping and Audit –

Award Recipients agree to maintain accurate and complete records of all monies received from NHF, all expenditures of said monies, and all inventions related thereto, for a period of three (3) years from the date of termination or expiration of this Agreement. Moreover, Award Recipients agree that NHF may conduct an audit of such records at any time during regular business hours as reasonably requested by NHF and with reasonable advance notice.
6. Change in Status

The Awards Recipient and his/her sponsor (or mentor) is expected to remain at their institution for the duration of the project. If the Awards Recipient, his/her sponsor or mentor leave their institution, the Award Recipient is responsible for notifying the NHF Research Department immediately.

The transfer of an Award Recipient’s project to another institution or investigator is at NHF’s sole discretion. Any changes in budget after a Award is awarded must be requested in writing and the justification must be explained in detail to NHF’s satisfaction. NHF retains sole discretion to reject or accept budget changes.

7. Scientific Misconduct and Fraud

The Award Recipient’s institution is responsible for having and instituting a written policy or guideline on conflict of interest and scientific misconduct and fraud. A copy of this policy must be supplied to NHF. It is the responsibility of the institution and the Award Recipient to inform NHF of any institutional investigation involving the conduct of an investigator funded by NHF. It is also the responsibility of the institution and IIRA recipient to keep NHF informed of the progress and outcome of the investigation. Findings of fraud or misconduct are sufficient grounds to terminate support of the funded project.

8. Termination of Support

NHF reserves the right to terminate support of a funded project at any time for any reason in its sole discretion by providing sixty (60) days written notice to the awardee. Within 30 days of the termination date, the Award Recipients shall deliver to NHF a final progress report, which shall include all scientific information available as of the termination date together with a final financial report. Unexpended funds shall be returned within forty-five (45) days.

NHF may at its option elect to terminate this Agreement in the event the Award breaches a material term of this Agreement, the Policies, or other obligation owed to NHF, and such breach remains uncured for 30 days after Award Recipient’s receipt written notice from NHF.

9. Publications and Presentations

Award Recipients are required to include an acknowledgment of NHF’s grant support (such as: This research was supported by a research grant through the National Hemophilia Foundation/Innovative Investigator Award) in all publications, including abstracts, which result from NHF funded research, whether or not NHF is the exclusive source of funding. Copies of all publications resulting from research funded by NHF must accompany progress reports. If publications or presentations occur after the final report is submitted, Award Recipients are responsible for updating NHF’s Research Department and for sending a copy of it.
NHF reserves the right to publish, reproduce, and distribute non-confidential material generated from all projects. All work including, but not limited to, videos, written reports, and other materials deriving from a project shall remain the property of NHF. In addition, NHF may ask an Awards Recipient to present their research at a future NHF Annual Meeting and/or summarize their research project for a future NHF publication. Notwithstanding the foregoing, the institution shall have a right to use the data resulting from the project for its internal educational and research purposes.

10. Availability of Research Results and Resources

Restricted availability of research results or resources upon which further studies are dependent can impede the advancement of research and the delivery of medical care. Therefore, results and resources developed while funded by an NHF grant must be made available for research purposes to qualified individuals within the scientific bleeding disorders community. Categories of these resources include but are not limited to synthetic compounds, organisms, cell lines, viruses, cell products, cloned DNA, DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data.

11. Inventions and Patents

All NHF grants are subject to NHF's policy on inventions, patents and works of authorship, set forth as follows. By accepting an award for a research project, the principal investigator and all other personnel contributing to and working on the project, as well as the institution(s) and investigator(s) with which they are affiliated, agree to be bound by the terms and conditions of NHF's Policy on Inventions, Patents and Works of Authorship.

NHF understands that patents and/or licensing agreements may be pursued on inventions resulting from research by the Award Recipient, supported in whole or in part by funds furnished by NHF; that such inventions shall be administered and licensed so that they are introduced into public use as soon as practicable; and that such result will be achieved through NHF's granting permission to patent and license such inventions. Accordingly, NHF adopts the following policies:

- An invention resulting from the support in whole or in part to the grant recipient of funds awarded by NHF (hereinafter "NHF Invention") shall be reported promptly in writing to NHF's Research Department. An "Invention" is any discovery, data, material, method, process, device, product, program, software, know-how or other work of authorship in which the Institution or Investigator has a proprietary interest, whether or not patentable or copyrightable, that is created, conceived, discovered or reduced to practice in the course of a Project, or arises within three (3) years after completion of a Project thereof and is made using funds provided by NHF.

- If the university or other research institution or an individual investigator(s) associated therewith ("Institution" or "Investigator") which is the Recipient of financial support for any work leading to the NHF Invention has an established patent and licensing policy
and procedure for procuring and administering inventions which are known to and accepted by NHF, or has an agreement with another organization, including agencies or departments of the U.S. government relating to the NHF invention due to joint support, NHF will defer to that policy or agreement subject to the following terms regardless of whether incorporated into a written agreement and/or referenced in a master agreement.

- With respect to any NHF Invention, the Institution or Investigator shall have the right to file a patent application, and if the Institution or Investigator decides not to file a patent application, shall have the right to file a patent application. In the event that any Institution or Investigator desires to file a patent or copyright application such Institution/investigator shall notify NHF immediately in writing and, upon NHF’s request, shall provide NHF with copies of all documentation relating to all such filings. NHF shall maintain the confidentiality of such documentation by executing a confidentiality agreement mutually agreed to by the Institution/investigator and NHF.

- NHF shall be notified promptly after a decision not to file for patent protection is reached, and with sufficient time to permit NHF to evaluate the NHF Invention and prepare and file for patent protection. NHF shall be granted a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for and on its behalf any invention claimed in any Institution-filed or NHF-filed patent application and on any patent obtained thereof or thereon. The patent application(s) and patent(s) obtained thereon shall embrace the United States, and countries outside of the United States as mutually agreed upon as between NHF and the Institution or Investigator. NHF Inventions shall include those made by employees or agents of the Institution or Investigator, alone or together with third parties, including third parties under the control of the Institution or Investigator.

- The Institution or Investigator will notify NHF in writing of any decision not to continue the prosecution of a patent application, pay maintenance fees, or defend a reexamination or opposition proceeding on a patent, in any country, not less than thirty (30) days before the expiration of response period or applicable deadline required by the relevant patent office. The grantee institution will convey to NHF, upon written request, title to any such patent application or patent. No patent or patent application shall be abandoned without prior notification to NHF and without giving NHF the opportunity to take title to the patent, application and Invention, to the extent permitted by law.

- The Institution or Investigator will make the invention available for commercial licensing upon reasonable terms and conditions. In the event that the Institution/investigator contemplates entering into a license or revenue-generating agreement relating to an Invention the terms of any such agreement shall be provided to NHF prior to execution so as to provide NHF the opportunity to provide comment and input. Any such agreement must include provisions requiring the licensee to exercise reasonable efforts to commercialize the Invention and the Institution shall monitor performance of the licensee.
NHF shall be granted a non-exclusive, royalty-free license to practice any Invention covered by said application and/or granted patent for non-commercial research purposes. This license will be subject to any restrictions on use or other limitations set forth in any agreement entered into between NHF and Institution/investigator.

From the Net Revenues received by the Institution from licensing a NHF Invention, NHF and the Institution or Investigator and other agreed upon parties shall share on terms mutually agreed upon by the Institution or Investigator and NHF, such terms to be determined prior to any licensing or commercial exploitation of the invention with NHF’s share being at least equal to the percent of total funding that NHF has provided to the Institution or Investigator support the specific research project through grants and awards but in no event shall NHF receive less than ______% of Net Revenues. "Net Revenues" shall mean gross proceeds received by Institution from the licensing of the NHF Invention less all reasonable and actual out-of-pocket costs (exclusive of any salaries, internal administrative, or other indirect costs) incurred by Institution in the licensing of the invention and the preparation, filing, prosecution, and maintenance of the associated patent rights associated direct out-of-pocket litigation expenses.

In the event that it obtains a patent, license arrangement or other commercial exploitation of a NHF Invention, the Institution or Investigator shall make periodic reports to NHF with respect to its and its licensee’s utilization of the invention and account for all income and/or other consideration received by it by reason of any exploitation of the invention.

If neither Institution nor its licensee has not taken effective steps within three years (or whatever is a reasonable longer time in the circumstances) after issuance of a patent or agreed upon determination of commercial value in an Invention that is being administered by the Institution to bring the Invention to practical or commercial application through licensing or otherwise on terms that are reasonable in the circumstances; and if, upon written request by NHF, neither Institution nor its licensee has provided reasonable cause why it or its licensee should retain title to and all rights in the administration of the Invention for a further period of time, then, unless no other parties have equal or superior rights, NHF may require the Institution to (i) license (on an exclusive basis where possible) said patent or intellectual property right to NHF with the right to grant sublicenses or (ii) compel reasonable disposition of the Invention rights as may be mutually agreed upon.

In the event of disputes between the Parties arising out of, or in connection with this Agreement related to inventions or patents, the Parties agree to attempt to resolve such disputes by good faith discussions by and among the senior individuals with responsibility for patent and licensing activities at the disputing Parties’ institutions, with advice of patent counsel, if necessary. Where disputes cannot be resolved by mutual agreement, the Parties agree to submit to non-binding mediation using procedures to be negotiated in good faith, with the intent
• If the Institution or Investigator has no patent or licensing policy and procedure for administering inventions, NHF shall have the sole right to determine the disposition and/or exploitation of rights in a NHF Invention.

12. Liability and Insurance

Award Recipient and Institution shall be responsible for all aspects of the research, investigation, funding, and administration of or in connection with the Research Project.

To the extent permitted under the international, federal, state, and local laws which govern the Award Recipient and Institution, the Award Recipient and Institution shall indemnify and hold NHF harmless from and against any and all costs, losses, or expenses, including reasonable attorneys’ fees, that NHF may incur by reason of the Award Recipient and/or Institution’s negligence or misconduct or any third-party claim arising out of or in connection with the Research Project.

In the event of any dispute arising out of this Agreement, the parties shall use good faith efforts to resolve their differences amicably. In the event they are unsuccessful, the parties agree not to commence litigation until attempting to resolve their dispute through mediation. Either NHF on the one hand or the Award Recipients on the other hand may initiate the mediation process with 30 days prior written notice to the other party. Mediation of the dispute shall be completed within 15 days of commencement, unless the parties extend the time by mutual agreement or unless the mediator declares the parties to be at an impasse.

Award Recipient’s Institution shall be required to maintain adequate liability insurance comparable to coverage held by institutions of similar size and nature, covering the Award Recipient and the Institution’s employees, officers, and agents of Institution for the duration of the Research Project. NHF may request to be provided certificates evidencing the insurance coverage at any time during the grant Term.

13. Human Subjects

The Award Recipient’s institution has the primary responsibility for protecting the rights and welfare of human subjects in any research activity supported by NHF. Award Recipients performing research involving human subjects must submit written approval of the research project from their institution’s Institutional Review Board. It is the responsibility of the Award Recipient and the institution to notify NHF of any changes to the research protocol involving human subjects.

14. Use of Animals in Research
NHF adheres to the most up-to-date guidelines applicable to the care and treatment of animals used in laboratory work as outlined by the National Institutes of Health (NIH). The NIH policy defines animals as “any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.” ([https://grants.nih.gov/grants/olaw/references/phspol.htm#Definitions](https://grants.nih.gov/grants/olaw/references/phspol.htm#Definitions), accessed 2/13/2018)

NHF adheres to the following principles regarding the use of animals in research:

- Animals shall be used in research only when no other means of obtaining scientifically sound, valid, and useful results are available.
- The minimum number of appropriate animals required to obtain and validate results shall be used.
- The acquisition, care, and use of animals must be in accordance with all applicable federal, state, and local laws and regulations.
- Certifications must be received from research facilities prior to being approved for a research grant that the facility(ies), its researchers, and employees adhere to the Animal Welfare Act, National Research Council *Guide for the Care and Use of Laboratory Animals*, the standards for laboratories established by the Association for the Assessment and Accreditation of Laboratory Animal Care International, and any appropriate U.S. Department of Agriculture or NIH regulations and standards. No funds will be awarded until documentation of these materials are received, reviewed, and approved by NHF.
- In cases requiring the death of an animal, only the most appropriate and humane form of euthanasia shall be used consistent with the purpose of the research.

It is the responsibility of the Award Recipients and their institutions to comply with these principles, national guidelines and to notify NHF of any changes to the research protocol involving animals.

15. Biohazards

The applicant, sponsor and sponsoring institution acknowledge that in their statement concerning potential Biohazards and the safeguards to be employed are accurate descriptions of the circumstances pertaining to this aspect of the research proposed in the application to NHF. Research involving recombinant DNA, bio-hazardous materials, genetically engineered mechanisms, human fetal tissues, and/or human anatomical substances (collectively “Biohazards”) must be reviewed and approved by the applicant’s institution and conform to the relevant U.S. Public Health Service (or international equivalent) guidelines. Projects which do not involve Biohazards must so state it. NHF assumes no responsibility or liability for any such biohazard and applicant, sponsor and sponsoring institution shall hold NHF harmless from all claims and damages arising out of the use of any such biohazard. Research involving the use of human specimens, cells, cell lines or data involving human subjects will comply with the applicable requirements of the National Institutes of Health Office of Extramural Research.

16. Assurance of Compliance
Award Recipients shall comply with all applicable laws and regulations in connection with their Award and shall cooperate fully with NHF in supplying additional information and complying with any procedures that might be required by a government agency in order for NHF to confirm its compliance with all requirements under the law with respect to any award.

17. General Provisions

All notices, requests, and other communications hereunder shall be in writing and shall be personally delivered or sent by recognized overnight courier, or by registered or certified mail, return receipt requested, postage prepaid, in each case to the addresses provided in the Application, or such other address as may be specified in writing to the other parties.

The interpretation and application of the provisions of this Agreement shall be governed by the laws of the State of New York.

Neither party may waive or release any of its rights or interest in this Agreement except in writing. The failure of a party to assert a right hereunder or to insist on compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other party.

In the event any one or more of the provisions contained in this Agreement should be invalid, illegal or unenforceable in any respect in any jurisdiction, the validity, legality and enforceability of such provisions shall not be affected or impaired in any other jurisdiction, nor shall the remaining provisions contained herein in any way be affected or impaired thereby.

Neither party shall represent itself as the agent or legal representative of the other for any purpose whatsoever and shall have no right to create or assume any obligation of any kind, express or implied, for or on behalf of the other party in any way whatsoever. This agreement provides for funding research consistent with NHF’s mission and accordingly nothing herein shall be construed to create or imply any relationship of employment, agency, joint venture, partnership, franchise or any relationship.

No provisions in this Agreement shall in any way inure to the benefit of any third party.

Any legal action or proceeding with respect to this Agreement shall be brought only in the courts of the State of New York or of the United States of America located in the State of New York and, by execution and delivery of this Agreement, each party hereby accepts for itself and in respect to its property, generally and unconditionally, the exclusive jurisdiction of the aforesaid courts. Each party hereby irrevocably and unconditionally waives any claim for special, consequential or punitive damages and any objection, including, without limitation, any objection to the laying of venue or based on the grounds of forum non conveniens, which it may now or hereafter have to the bringing or maintaining of any such action or proceeding in such respective jurisdictions.

This Agreement constitutes the entire agreement and understanding between the parties, and neither party shall be obligated by any condition, promise or representation other than those expressly stated herein or as may be subsequently agreed to by the parties hereto in writing.
The undersigned parties represent and warrant that each has full authority to execute this Agreement on behalf of themselves, their predecessors and all other persons and/or entities named herein.

The terms of Sections 1, 4, 5, 9, 11, 12 and 17 of this Agreement shall survive the expiration or termination of this Agreement.

This Agreement may be executed by the parties hereto in counterparts, including by facsimile transmission, each of which when so executed shall be deemed an original and all of which together shall constitute one and the same Agreement.