



NATIONAL MPS SOCIETY RESEARCH INITIATIVE POLICIES AND AGREEMENT

MISSION

The National MPS Society exists to find cures for MPS and related diseases. We provide hope and support for affected individuals and their families through research, advocacy and awareness of these devastating diseases.

PURPOSE OF RESEARCH GRANTS

The purpose of the National MPS Society's Research Initiative is to:

- Focus on central nervous system and bone and joint complications in MPS diseases
- Focus on translational research
- Support new researchers
- Secure funding sources

REVIEW OF APPLICATIONS

- **January:** Determination of grants to be offered based upon available funding
- **February:** Request for letters of intent e-mailed to researchers
- **March:** Letters of intent submitted
 - Review committee from Scientific Advisory Board (SAB) reviews letters of intent
 - Researchers are selected to submit full grant proposals
- **May:** Grant proposals submitted
 - SAB review committee reviews grant proposals
 - Recommendation of grants to be funded submitted to the Society's Board of Directors Research Committee
- **June:** Final recommendation of grants to be funded submitted to full Board of Directors for approval
 - Letters sent to first year grant recipients to request review of research and budget. Second year funding awarded upon submission of reports.
- **July:** Grants are funded

SOURCE OF FUNDS

The primary source of funding for the Research Initiative is the Society's annual walk/runs, events hosted by member families. Additional funding is received from individual

donors, foundations and other philanthropic sources. These donors are acknowledged through private correspondence, in Society publications, at Society conferences and other public meetings and events.

APPLICANT CITIZENSHIP

The research grants are internationally inclusive and open to scientists throughout the world, working independently and collaboratively.

BASIS AND AMOUNT OF AWARD

Awards are determined in January of each year, both the number and focus of award, with amounts being determined by available funds in that grant cycle.

TERMS OF AWARD

Awards are for two years, with possibility of no-cost extension up to one year for unforeseen problems or exceptional opportunities. The no-cost extension is subject to review and approve of the Research Committee

At the end of an award, with the final report and final budget, any unused monies should be returned by the receiving institution to the National MPS Society.

RESEARCH AWARD ASSURANCE

Compliance with all human subjects, laboratory animal, recombinant DNA, etc., regulations.

REPORTS

Progress reports are required at the end of both the first and second years of funding. If a no-cost extension is allowed, a final report is required after that period.

Included in the reports are: summary of work to date in lay terms (to be published in the Society's quarterly newsletter *Courage* and on the Society's website), description of experiments, results, conclusions, future work, and publications. A separate budget report is due at the end of each year.

Send reports to:

Barbara Wedehase, Executive Director

National MPS Society

PO Box 14686

Durham, NC 27709-14686

p: 919.806.0101

f: 919.806.2055

E-mail: Barbara@mpssociety.org

If intellectual property is contained in the reports, the National MPS Society agrees to keep the reports confidential to allow the grantee or primary investigator the appropriate time to protect this IP.

ALLOCATION AND EXPENDITURE OF FUNDS

Funds will provide direct support for the research proposal but will not be used to underwrite the senior scientists' regular salaries. Funds may be used for equipment essential to the project and for specified consumable supplies.

INDIRECT COSTS

No institution overhead or other indirect costs will be paid.

PAYMENTS

Grant payment will be made at the inception of the project, upon receipt of a clinical research agreement signed by the principle investigator (PI) and an officer of the receiving institution. The second year funding will be made following receipt of the one-year interim progress report and budget summary. **Second year funding will be permanently cancelled if the interim reports are not received six (6) months following completion of the first year research.** All payments will be made to the institution, as indicated in the clinical grants agreement.

FINANCIAL RECORDS

The PI is expected to keep on file accurate financial records that tie directly with all budget reports submitted to the Society.

CANCELLATION OF GRANT

The National MPS Society reserves the right to cancel the grant if the PI is unavailable to continue work and no change of investigator is available to carry on work exactly as proposed at that institution, or if PI leaves institution for another, or, if no progress is made after the maximum project duration of 36 months including a twelve month no cost extension. In any of these cases the institution/PI is obligated to return funds

CHANGE OF PRINCIPAL INVESTIGATOR

If the PI leaves Grantee institution, another PI may be available to supervise the research subject to the approval of qualifications by the National MPS Society Scientific Advisory Board research grant committee.

INTELLECTUAL PROPERTY RIGHTS

I. **POLICY STATEMENT.** Part of the National MPS Society's mission is to facilitate the development and implementation of novel treatments and preventive measures for MPS and related diseases. The Society has therefore adopted this intellectual property policy with the intention of encouraging commercialization of inventions made with its support.

II. **DEFINITIONS.** The following terms shall have the meaning set forth below.

- a. "Funded Research" shall mean the research funded by Society.
- b. "Investigator" shall mean the principal investigator(s) of the Funded Research.
- c. "Institution" shall mean the Investigator's organization in which the Funded Research is conducted.

- d. "Invention" shall mean any discovery, material, method, process, product, program, software or use, whether or not patented or patentable or copyrighted or copyrightable made in the course of the Funded Research.
- e. "Public Disclosure" shall mean any publication, presentation, offer for sale or any activity that would affect the patentability of the invention under U.S. or Foreign laws.
- f. "Net Revenue" shall mean gross revenue received by Institution in respect of an Invention less unreimbursed directly assignable out-of-pocket expenses resulting from patenting and licensing of that Invention.

III. OWNERSHIP OF INVENTIONS. Institution shall have in place a policy requiring the Investigator and any other Institution employee or other person under its control who makes a contribution to the Invention to promptly report the Invention to Institution and to assign all of his or her rights in the Invention to Institution. Subject to any rights of the U.S. government or collaborating sponsor of the Funded Research, all Inventions shall be owned by the Institution. Institution shall disclose to the Society all details of each Invention at least thirty (30) days prior to its first Public Disclosure and no later than fifteen (15) days from being notified of the Invention. Institution shall promptly determine whether it desires to seek patent or other legal protection for each Invention. Institution shall notify the Society should it decide to seek patent or other legal protection for an Invention. Thereafter, Institution shall keep the Society fully informed of the status and progress of all patents, patent applications, copyrights, and copyright applications for the Invention. Institution shall be solely responsible for all costs and expenses incident to obtaining and maintaining legal protection for the Invention. Should Institution decline to seek, abandon seeking, or decline to maintain all available patent or other legal protection for an Invention, Institution shall immediately notify the Society and allow and cooperate with the Society to seek or maintain such legal protection in its own name. Should the Society choose to seek or maintain such legal protection, Institution shall assign its rights to such legal protection for the Invention to the Society. The National MPS Society grants to Institution a non-exclusive license to use any such assigned Invention for Institution's internal non-commercial research purposes only. The Society shall have no obligation to Institution, Investigator, or any person controlled by Institution regarding the further disposition of any rights assigned to it.

IV. PUBLICATION. Institution shall have the right to publish the results of the Funded Research so long as Institution provides a copy of the intended publication at least thirty (30) days prior to its submission to any third party and acknowledges that the Funded Research was supported by a grant from the National MPS Society. Institution shall postpone any intended publication of the results of the Funded Research for an additional thirty (30) days if so requested by the Society to allow one or more patent applications to be filed for any Invention(s) disclosed in the intended publication.

V. LICENSING. Institution hereby grants the Society a non-exclusive license sublicensable to any of Society's grantees to use any Invention for research purposes only. Within three (3) years from the disclosure of an Invention to the Society, Institution shall license the Invention to a suitable entity under a license agreement including royalty, due diligence, and indemnification terms typical for technology license agreements between academic organizations and industry. Institution shall provide a copy of any such licensing agreement to the Society for approval at least thirty (30) days prior to its execution. Should Institution fail to license an Invention within three (3) years from the disclosure of the Invention, Institution shall immediately notify the Society and offer to assign to it for no fee or cost all of Institution's rights to the Invention including any patents, patent applications, copyrights, copyright applications, and contracts related thereto. Should Net Revenue from an Invention exceed \$200,000, Institution shall pay the Society annually a royalty equal to five percent (5%) of the Net Revenue from the Invention. Any payment made hereunder shall be accompanied by an appropriate statement of account detailing the amount and showing the calculation of Net Revenue received by Institution during the preceding year. The Society shall have the right to audit the Institution's books and records annually, in order to verify the Net Revenue derived annually from any Invention.

VI. INFRINGEMENT. A party shall notify the other party promptly after becoming aware of infringement of any intellectual property rights in an Invention owned by Institution but neither party shall be obligated to pursue litigation to enforce any intellectual property rights in an Invention. Should Institution decline to pursue such litigation, it shall promptly notify the Society and provide the Society the opportunity to pursue such litigation in Institution's name and with Institution's cooperation. Should the Society pursue such litigation, it shall be responsible for all of its costs related thereto and shall be entitled to any and all damages recovered therefrom.

VII. CONFIDENTIALITY. The National MPS Society shall maintain the confidentiality of an Invention disclosed to it until a patent application for the Invention is filed or the Invention is disclosed to the public by Institution or another party which did not learn of the Invention from the Society. This obligation shall not apply if the Invention (a) was lawfully known by the Society prior to its disclosure from Institution; (b) was or becomes generally available in the public domain, without the fault of the Society; (c) is subsequently disclosed to the Society by a third party having a lawful right to make such disclosure; (d) is required by law, rule, regulation or legal process to be disclosed; or (e) has been independently developed by employees or others on behalf of the Society as demonstrated by written record. This obligation shall extend for a period of three (3) years from the initial disclosure of the Invention to the Society.

VIII. DISPUTE RESOLUTION. Neither party shall file a lawsuit against the other relating to the terms of this policy, without first providing the other party thirty (30) days advance written notice of the intended lawsuit to the other party. Within ten (10) days of

the date of such notice, the parties shall meet and engage in good faith negotiations to resolve such dispute. Should the parties not agree on an amicable solution to the dispute within thirty (30) days from the initial notice, each party shall be free to seek any remedy available to it in a court of law or administrative body.

IX. ENTIRE AGREEMENT. This policy constitutes the full understanding between the parties with reference to the subject matter hereof, and no statements or agreements by or between the parties, whether orally or in writing, shall vary or modify the written terms of this policy. Neither party shall claim any amendment, modification, or release from any provisions of this policy by mutual agreement, acknowledgment, or otherwise, unless such mutual agreement is in writing, signed by the other party, and specifically states that it is an amendment to this Policy.

PUBLICATION

The National MPS Society has the right to review any publications/abstracts/web postings on results and IP potential of funded research before it is sent out/posted with time limit for review.

PUBLICITY

The National MPS Society has the right to publicize supported research. Grantee is not to use name of National MPS Society without permission, except to identify the National MPS Society as source of research funds in publications.

PRINCIPLE INVESTIGATOR

INSTITUTION ADDRESS

RESEARCH TITLE

AMOUNT OF AWARD

Principle Investigator

Date

Dean or Head of Institution in Behalf of Institution

Date

National MPS Society Executive Director

Date

DRAFT