

## **POLICIES ON AWARDS FOR RESEARCH ON FSHD**

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#### 1. THE AWARD PROGRAM

The FSHD Society, Inc. (the “Society”) sponsors research programs to meet needs of critical importance in the research and clinical efforts of facioscapulohumeral muscular dystrophy (“FSHD”).

#### 2. PEER REVIEW OF APPLICATIONS

The Society’s Scientific Advisory Board (SAB) and/or Therapeutic Accelerator and Research Committee (TARC) evaluate: (a) the scientific merit of the application, (b) the qualifications, experience and productivity of the applicant, (c) the facilities and resources available to the applicant, and (d) the promise of the research as related to the cause(s) of FSHD or to the benefit to be gained by persons with FSHD. After considering the applications, the amount of available funds and the Society's objectives, committee makes its recommendations to the Board of Directors (BoD) which, in turn, determines which applications will be accepted and recommended for Award funding.

#### 3. ELIGIBILITY FOR AWARDS

Anyone proposing to do research on FSHD may apply for an Award. Applicants may be residents of any country. Awards are made directly to the individual (a “Grantee”) or to the non-profit training and/or research institution where the Grantee is being trained or employed and conducting the research covered by the grant or fellowship (the “Grantee Institution”).

Grantees are not employees of the Society and are not eligible to receive any benefits or compensation from the Society, except as expressly stated in writing in the Award.

The Society does not assume responsibility for the conduct of the research or the acts of the Grantee.

The Grantee and Grantee Institution must safeguard the rights and welfare of individuals who participate as subjects in research activities by reviewing proposed activities through an Institutional Review Board (“IRB”), if applicable, as specified by the National Institutes of Health (“NIH”) Office for Protection from Research Risks, or the equivalent standard of the country in which the research is conducted. Furthermore, the Grantee and Grantee Institutions must adhere to current United States Department of Health and Human Services guidelines regarding financial conflicts of interest, recombinant DNA, research misconduct, and vertebrate animals, or the equivalent applicable laws and regulations of the country in which the research is conducted.

It is the intent and expectation of the Society that all Award recipients shall use the Award to institute or continue research that will provide the basis for applications for further research funding from other sources, such as NIH. Decisions on future Award funding from the Society will take into consideration whether applications have been made to other funding sources.

#### 4. DESCRIPTION OF AWARD

Awards are designed to enable new or continued research. An application for an Award must be signed by the applicant and the applicant’s proposed mentor or the Principal Investigator in the department in which the research will be conducted. A plan and budget for the use of Award funds must be formulated and agreed on by the applicant and the mentor or the Principal Investigator and described in detail in the application.

#### 5. TERM AND EXTENSION

The initial term (“Term”) for an Award can be variable, and there is no guarantee such Term will be extended or that additional funding will be provided after the Term. Funding to extend the Term is dependent upon the satisfactory outcome of the review of the interim and final report by the Society and the Board of Directors’ approval of the recommendation made by Society and is subject to the availability of funds. Upon written request by the Grantee to the Society, an extension of the Term (No Cost Extension (NCE)) may be obtained with the consent of the Society without additional funding beyond the initial and agreed-upon budget.

#### 6. FUNDS

An Award consists of a stipend, an institutional allowance, and possible travel allowance to the Society’s International Research Conference. Requests for relocation travel and institutional allowances will be considered only if included in the application at the time of submission.

A. Stipend. The annual stipend may be used only for compensation of the research applicant. The Society does not withhold any amount for income taxes, social security or any other taxes and a Grantee is responsible for the payment of all applicable federal, state and local taxes.

B. Institutional Allowance. See Section 7.A, below.

C. Travel Allowance for Relocation. Where applicable, funds may be requested to defray the cost of the Grantee’s travel to the Grantee Institution. If the Grantee is working at the Grantee Institution at the time of the application, no travel funds are allowed. Funds will not be provided for

travel by dependents. Support for travel to meetings may not be requested here.

## 7. INSTITUTIONAL EXPENDITURES

A. Benefits. The Awards includes coverage for health insurance or similar benefits provided by the Grantee's institution in an amount proportional to the Grantee's allocated time outlined in the project's budget description. These benefits are not to exceed thirty-five percent (35%) of the portion of the Grantee's base salary from the Grantee Institution that is covered by the Award. Reimbursement for the cost of benefits does not entitle the Grantee to receive from the Society, or obligate the Society to provide, such benefits or any other benefits, and does not create any employer-employee relationship. Awards do not include funds for supplies, space, or equipment unless otherwise agreed upon.

B. Limitations on Overhead. Awards are not designed to cover the total cost of the research proposed or the investigator's entire compensation. Expenditures on overhead are limited to ten percent (10%) of the Award on grants and no overhead expenditures are to be allocated for fellowships.

C. Supplemental Funds. Special consideration for supplemental funds or a modification of the initially agreed upon budget may be given to the Grantee, with prior written approval from the Society, for capital equipment, non-laboratory supplies or scientific consumables, rental of office or laboratory space, recruiting and relocation expenses, non-medical services to patients, per diem charges for hospital beds, construction, renovation, or maintenance of buildings/laboratories directly related to the purpose of the Award. Requests for such consideration must be made in writing to the President and CEO of the Society.

## 8. PAYMENTS

Stipend payments are made directly to the Grantee (or to the Grantee Institution if requested in writing by the Grantee), in multiple disbursements, including a final payment due upon completion of the Award project. Typical instalments include an initial payment of 30-50% at the start of the Award, followed by equal instalments following the approval of each progress and final report.

## 9. RECORDS AND REPORTS

### A. Financial.

1) The Term for an Award starts on the first day of the month following the receipt of the signed agreement from the Grantee if received prior to the 15th of the month, and, if received on or after the 15th, on the first day of the second month following receipt. The signed agreement should identify whether the Grantee or the Grantee Institution is the recipient of the payment. The check for the first installment of the Term will be issued promptly.

2) Separate accounting must be maintained for each Award.

3) A final financial report, signed by the Grantee and the Grantee Institution, must be

submitted within 90 days after the completion or termination of an Award, together with the refund of any unexpended balance.

**B. Scientific Progress Reports.**

1) Interim Report - The Grantee must submit to the Society a scientific report of results addressing the research accomplished relative to the deliverables outlined in the proposal. Results, unexpected setbacks or changes that might impact the satisfactory completion of the program should also be addressed. This report will be maintained in strict confidence by the Society.

2) From time to time, at the request of the Society, Grantees will be expected to give brief presentations of their research to professional or lay audiences. The Society also expects Grantees to attend the Society's International Research Conference and present their research project to the scientific community.

3) A final scientific report, signed by the Grantee and the mentor or the Principal Investigator at the Grantee Institution, must be submitted to the Society upon completion or termination of an Award.

4) All reports must be in English and must include a summary in layman's terms.

**10. LIABILITY**

Grantee shall assume all responsibility for injury or other damage relating to the Award.

**11. PUBLICATIONS**

Copies of accepted manuscripts for publications resulting, in whole or in part, from the research supported by the Award shall be provided to the Society as soon as practical, including publications after the expiration of the Award. Publications must contain an acknowledgment of the Society as follows: "Supported by FSHD Society Research Grant #\_\_\_\_\_".

**12. CANCELLATION**

The Society reserves the right to cancel an Award for failure to materially carry out its terms and conditions. In such event, the Society shall provide written notice to the Grantee of termination. The Grantee shall have 30 days in which to appeal the cancellation of the Award. Cancellation decisions shall be made by the Society.

In the event an Award is cancelled, the Society will not be responsible for expenditures in excess of payments already made to the Grantee or the Grantee Institution prior to the effective date of cancellation. To the extent they do not exceed the Award, all unexpended funds must be returned to the Society. If an Award is to be canceled by the Grantee, the Grantee shall inform the Society immediately, provide an accounting of all funds expended and return any unexpended funds.

### 13. CHANGE OF GRANTEE INSTITUTION/MENTOR/PRINCIPAL INVESTIGATOR

Awards are given on the basis of individual and institutional merit and, therefore, are not transferable either with respect to the Grantee Institution or the mentor or the Principal Investigator without prior written approval from the Society. The replacement of the Grantee Institution is contingent on the new Grantee Institution indicating acceptance of the Award and documenting the existence of the appropriate resources and mentor or Principal Investigator for the Grantee to continue their research. Payments to the new Grantee Institution will not be initiated until a final accounting and a check for any unexpended funds have been received from the original Grantee Institution and the transfer has been approved by the Society. Requests for a replacement of the Grantee Institution or the mentor or the Principal Investigator must be sent to the President and CEO of the Society.

### 14. PATENTS AND NON-EXCLUSIVE LICENSE

As a not-for-profit organization supported by public contributions, the Society believes that potentially beneficial discoveries are developed regardless of their commercial profitability.

The Society's patent policy is designed to ensure that such discoveries are brought to practical application with regards to the field of curing, diagnosing, and/or treating FSHD and its complications and to provide the Grantee Institutions responsible for them with sufficient flexibility regarding the funding of research and the patenting and developing of any discoveries made thereunder.

A. Inventions. Discoveries conceived during the Term, reduced to practice within twelve (12) months of Society funding, or further developed in the performance of, or as a direct result of, an Award (an "Invention") shall be promptly reported to the Society, and copies of any and all patent applications, invention disclosures, supporting documents and other pertinent materials shall be provided to the Society. The preparation, filing and maintenance of all patents resulting from Award funding shall be the sole responsibility, and under the sole control, of Grantee and Grantee Institution.

B. Patent Policy. The Society will defer to the established patent policy of the Grantee Institution.

C. Commercial Licenses.

1) Notice of Intention to Award Licenses or Other Transfers. The Grantee Institution shall provide the Society with written notice of its intention to option, transfer, sell, license, assign or otherwise award any party the exclusive or non-exclusive right to use or practice an Invention (hereinafter collectively a "License") at least thirty (30) days prior to awarding such License. Such notice shall describe in reasonable detail the proposed License to be awarded.

2) Non-Exclusive Licenses of Patentable Inventions. With respect to each or any intellectual property rights claimed in respect of such Invention, the Grantee Institution shall, upon the request of the Society, grant to the Society a non-exclusive, paid-up, irrevocable, perpetual license throughout the world for FSHD Research and Development including a license to (A) make, have made, use and have used products or processes resulting from such Invention, (B) practice and have practiced such



Invention. The foregoing license (1) shall be for FSHD Research and Development only, (2) shall not include any right to manufacture for sale or sell (including any transfer of services or products made using intellectual property rights, whether or not for consideration, other than a transfer of services or products solely for research and development purposes without fee or profit), (3) shall not be subject to royalties or other fees and (4) shall include the right to grant sublicenses on the same terms; provided, that, such sublicense a) is granted without payment of royalties, other fees or profit and b) prohibits the sublicensee from granting sublicenses.

#### 15. PROTOCOL FOR DISTRIBUTION AND SHARING OF MATERIAL

The Society expects that Grantees will support its goal of the widest possible distribution of the results of supported research. Therefore, Grantees will be expected to (a) publish or make public, through public presentations or the equivalent, the results of their research in a timely manner and (b) assist other researchers by providing cell lines and other material substances reasonably designed to promote the research of other scientists. Grantees are encouraged to consult with the Society to determine acceptable protocols for the sharing of such material.