

## **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”).

Each year, the Society will accept requests for research funding. All proposals are subject to peer review to identify the most meritorious and innovative to be funded.

#### 2. PEER REVIEW OF APPLICATIONS

The Society’s Scientific Advisory Board (the “SAB”) distributes the applications to the appropriate peer review committee of the SAB for initial scientific review. This committee evaluates: (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, the peer review committee makes its recommendations to the SAB 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 is one year, 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 beyond one year is dependent upon the satisfactory outcome of the review of the six-month and twelve-month 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 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 three disbursements per year, with 50% of the projected first year budget at the beginning of the Award, followed by equal installments of the remaining budget at six-month interval, with the final payment due upon completion of the Award project. Institutional allowances, if any, are paid at the start of the Award.

## 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 initial six (6) months 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) At six (6) month intervals, 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 within 90 days after the 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 practicable, 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, and 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, REQUIRED EFFORTS AND ROYALTIES

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 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 provided that any patent or patent application for an Invention will not be abandoned without the Grantee Institution promptly notifying the Society and, to the extent the Grantee Institution is legally able to do so and has determined there are no other viable means of making the Invention available for commercialization, permitting the Society the opportunity to take title and pursue the patent application for Invention at its own expense.

C. Required Efforts. Grantee Institution shall use good faith efforts, at its sole expense, to develop and commercialize an Invention in a timely fashion, either itself or through one or more licensees in the field of curing, diagnosing, and/or treating FSHD and its complications. Grantee Institution shall prepare and maintain (and shall cause its licensees to maintain) complete and accurate records regarding the development and commercialization of products claiming an Invention. Grantee Institution shall promptly and thoroughly respond to the Society's requests for information regarding such licensing or commercialization efforts.

If the Society determines in good faith, after consulting with the Grantee Institution, that the Grantee Institution has not itself or through one or more licensees diligently pursued commercialization of any

Invention in the field of curing, diagnosing, and/or treating FSHD and its complications within a reasonable period of time, then at the Society's request, the Grantee Institution shall meet with the Society to discuss a commercialization plan for the Invention that is reasonably satisfactory to both Society and Grantee .

D. Diligence Requirements for Licenses. Grantee Institution agrees that it will include appropriate diligence provisions in any exclusive license agreement for an Invention, as determined by Grantee Institution, to effectuate the expeditious development of an Invention for the public benefit (to include diligence provisions toward the cure, diagnosis, and treatment of FSHD, as appropriate, based upon the nature of the Invention) and will reserve the right to terminate any exclusive license it awards to an Invention if such diligence provisions are not met. Grantee Institution will monitor such diligence requirements and take effective steps as it deems appropriate.

E. 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) Sharing of Net Royalty Income. The Grantee Institution shall pay to the Society five percent (5%) of Grantee Institution's share of Net Royalty Income from commercializing an Invention up to an aggregate amount equal to five (5) times the Award Amount when the Net Royalty Income for such Invention exceeds two-hundred and fifty-thousand dollars (\$250,000). "Award Amount" means the total funding provided by the Society to Grantee Institution in connection with the grant under which the applicable Invention was developed "Net Royalty Income" means gross receipts (including the value of property or the portion of capital stock determined in accordance with the foregoing) received by the Grantee Institution from a third party from the licensing, sale, transfer or other commercial utilization of an Invention (whether at the time of License or subsequently attributable to an Invention) minus (i) all direct, unreimbursed costs leading to the Invention (including all patent and licensing costs and the full recovery of any indirect costs under the applicable Facilities and Administrative (F&A) rate) and (ii) payments to inventors of an Invention in accordance with Grantee Institution's published policy. The Grantee Institution shall make all such payments to the Society within ninety (90) days after Net Royalty Income is received by the Grantee Institution. The Grantee Institution shall provide to the Society, upon request, financial information adequate to establish and document the amount of Net Royalty Income. The Society shall have the right, at its own expense, to audit the Grantee Institution's records annually in order to verify the Net Royalty Income. The Grantee Institution's obligation to pay royalties to the Society shall survive after funding has terminated.

3) If the Society and the Grantee Institution are unable to mutually agree upon the calculation of Net Royalty Income for an Invention after good faith negotiations, such share shall be determined pursuant to mediation.

4) Either party may seek resolution of the dispute in a court of competent jurisdiction.

## 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 and SAB to determine acceptable protocols for the sharing of such material.