

FSH SOCIETY POLICIES ON FELLOWSHIPS AND GRANTS FOR RESEARCH ON FSHD

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1. THE FELLOWSHIP AND GRANTS PROGRAM

The FSH Society, Inc. (the “Society”) sponsors research programs to meet needs of critical importance in the research 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.

The following programs are available to support research efforts:

- A. Research Fellowships -- provide support for graduate student researchers at any stage of their research career.
- B. Targeted Project Research Grants -- provide one-time support for research projects proposed by investigators at any stage of their independent research career.
- C. Research Opportunity Grants -- provide rapid, one-time funding of novel ideas for finding a solution to urgent problems with immediate human benefit.

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 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 funding.

3. SOURCE OF FUNDS

The Society's funds are obtained principally from donations by individuals and organizations. The amount available for fellowships, grants and awards each year is contingent upon various factors, including the previous year's donations and the Society's funds on hand and anticipated expenses.

4. ELIGIBILITY FOR FELLOWSHIPS AND GRANTS

Anyone proposing to do research on FSHD may apply for a fellowship or grant. Applicants may be residents of any country. Fellowships and grants are made directly to the individual (a "Grantee") or to the non-profit training and/or research institution where the individual is being trained or conducting the research covered by the grant or fellowship. "Grantee Institution" means either (a) the institution(s) where a Grantee is being trained or conducting the research covered by a grant or fellowship, or (b) the institutional recipient of a grant. Recipients of these fellowships and grants may train at domestic or foreign not-for-profit institutions and at federal laboratories.

Recipients of grants and fellowships from the Society 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 grant or fellowship award.

The Society does not assume responsibility for the conduct of the investigation or the acts of the investigator, since both are under the direction and control of the Grantee Institution and subject to the institution's medical and scientific policies. 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") as specified by the National Institutes of Health ("NIH") Office for Protection from Research Risks ("OPRR"), 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 conflict of interest, recombinant DNA, research misconduct, and vertebrate animals, or the equivalent national standard of the country in which the research is conducted.

It is the intent and expectation of the Society that all grant recipients shall use the grant to institute or continue research that will provide the basis for applications for further research funding from other sources such as NIH. It is the desire and expectation of the Society that the Grantee shall file an application for research funding with such other sources prior to the end of the grant period. Decisions on future grants from the Society will take in to consideration whether such applications have been made.

5. DESCRIPTION OF FELLOWSHIPS AND GRANTS

Fellowships and grants are designed to enable new or continued research. An application for a fellowship or grant 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 for use of fellowship and grant funds must be formulated and agreed on by the mentor or the Principal Investigator and the applicant and described in detail in the application.

6. TERM AND EXTENSION

All fellowships and grants are initially funded for one time only, and there is no guaranteed funding of extensions of the fellowship or grant or renewal beyond its original terms. Each funded grant is for a specific amount and for the duration of one year. Funding for additional years is dependent upon the satisfactory outcome of the review of the nine-month report by the SAB, with the Board of Directors' approval of the recommendation made by the former, and is subject to the availability of funds. With prior approval of the Society, an extension of time may be obtained but there will be no additional funding beyond the initial and agreed-upon budget.

7. APPLICATION DEADLINE

There are no deadlines for the filing of fellowship and grant applications. Meritorious proposals are funded as resources and time permit at the sole and absolute discretion of the Society.

An applicant whose fellowship or grant application was rejected is encouraged to discuss with the Society the feasibility of a revised application. Revised applications will be reviewed in the same detail and compete on an equal basis with new applications.

8. FUNDS

A fellowship or grant consists of a stipend, an institutional allowance, and, when applicable, a travel allowance. 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. The applicant should contact his or her accountant to determine the tax status of the fellowship or grant. The Grantee Institution may supplement the fellowship or grant from other sources.

B. Institutional Allowance: See Section 9 A, below.

C. Travel Allowance for Relocation: Funds may be requested to defray the cost of the applicant's travel from the present institution to the training institution. If the applicant is working at the training 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.

9. INSTITUTIONAL EXPENDITURES

A. Institutional expenses normally allow for fellowships and grants to include reimbursement for part of the cost of health insurance or similar benefits in an amount not to exceed 15% of the portion of the fellow's or grantee's base salary from the Grantee Institution that is covered by the fellowship or grant. 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. Fellowships and grants do not include funds for supplies, space, or equipment unless otherwise agreed upon.

B. Society fellowships and research grants are not designed to cover the total cost of the research proposed nor the investigator's entire compensation. The Grantee Institution is expected to provide the required physical facilities and administrative services. The Society's fellowships and research grants do not provide funds for such items as secretarial/administrative salaries, tuition or foreign travel (with the possible exception of funds for relocation).

C. 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 attendance at scientific meetings related directly to the fellowship or grant, the acquisition of books and periodicals, cost of membership dues, office and laboratory furniture, office equipment and supplies, 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. Requests for such consideration must be made in writing to the President and CEO of the Society.

10. PAYMENTS

Stipend payments are made directly to the Grantee (or to the Grantee Institution if requested in writing by the Grantee), semi-annually, once at the beginning of the fellowship or grant and at six-month intervals thereafter. Institutional allowances, if any, are paid at the start of the fellowship or grant.

11. RECORDS AND REPORTS

A. FINANCIAL

A fellowship or grant starts on the first day of the month following the receipt of the signed agreement from the fellow or 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 individual or the institution is the recipient of the payment. At this time the first check for a six (6) month period will be issued.

Separate accounting must be maintained for each fellowship or grant. The Grantee and Grantee Institution must retain substantiating invoices and payrolls at all times for audit by representatives of the Society. Expenditures must be reported to the Society on a regular basis. At six (6) month intervals a short financial report shall be submitted by the Grantee or Grantee Institution to the Society.

A final financial report, signed by the Grantee and the Principal Investigator or mentor at the Grantee Institution, must be submitted within 60 days after the completion or termination of a fellowship or grant, together with the refund of any unexpended balance.

B. SCIENTIFIC PROGRESS REPORTS

In the ninth month of each fellowship or grant year, the Grantee must submit to the Society a scientific report of the research accomplished and any results, unexpected setbacks or changes that might impact the satisfactory completion of the program.

Additionally, the Grantee may submit, at three (3) month intervals, a brief progress report with a summary of the research accomplished.

In addition, Grantees will be expected to give brief presentations of their research to professional or lay audiences from time to time.

A final scientific report, signed by the Grantee and the Principal Investigator or mentor at the Grantee Institution, must be submitted to the Society within 60 days after the completion or termination of a fellowship or grant, together with publications and manuscripts in progress resulting from the research supported by the grant or fellowship.

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

12. PUBLICATIONS

Copies of publications resulting, in whole or in part, from the research supported by the fellowship or grant shall be provided to the Society as soon as practicable, including publications after the expiration of the fellowship or grant. Publications must contain an acknowledgment of the Society such as: "Supported by Research Grant #... from the FSH Society, Inc."

13. CANCELLATION

The Society reserves the right to cancel a fellowship or grant for failure to materially carry out the terms and conditions of the fellowship or grant. 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 fellowship or grant. Cancellation decisions shall be made by the SAB. Appeal shall be heard by the Society's Board of Directors. All costs associated with a cancellation appeal by the Grantee shall be borne by the Grantee.

In the event a fellowship or grant is canceled, 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, and all unexpended funds must be returned to the Society. If a fellowship or grant 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.

14. CHANGE OF GRANTEE INSTITUTION / MENTOR/PRINCIPAL INVESTIGATOR

Only after receiving written approval from the Society may recipients of a fellowship or grant from the Society transfer their fellowship or grant from one Grantee Institution to another or change their mentor or Principal Investigator.

A. Change of Grantee Institution. Prior to a transfer, the Society must receive the following:

(a) The request for transfer, in writing, indicating the anticipated transfer date, the reason for the transfer and a statement from an authorized administrative official at the original Grantee Institution relinquishing the fellowship or grant.

(b) The final Report of Expenditures together with a check for unexpended funds from the original Grantee Institution. This report must be submitted within sixty days after the date the transfer was requested.

(c) The application form completed by the appropriate individuals at the new Grantee Institution indicating acceptance of the fellowship or grant and documenting the existence of the appropriate resources and Principal Investigator or mentor. 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.

B. Change of Principal Investigator or mentor. Change of Principal Investigator or mentor for the recipients of fellowships or research grants will be considered on a case-by-case basis. Contact the President and CEO of the Society for further information. If a change in Principal Investigator or mentor also involves a change in project and/or Grantee Institution, a new application may be required.

15. PATENTS

As a not-for-profit organization supported by public contributions, the Society believes it has the responsibility to adopt necessary safeguards to make reasonably certain that potentially beneficial discoveries are developed regardless of their commercial profitability.

The Society's patent policy is designed to insure 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. Patentable discoveries conceived or reduced to practice in the performance of a Society fellowship, grant or other 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.

B. The Society will defer to the established patent policy of the Grantee Institution provided:

(a) such established policy is consistent with the purposes and obligations of the Society; and

(b) the patent application and the patent for Invention, if subsequently granted, will not be sold or assigned without written approval from the Society; and

(c) the patent application for 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.

Grantee Institution will be responsible for final licensing decisions regarding the Invention and agrees that during the marketing and licensing process of any Invention to a third party for commercialization, and during the period of any license, it will:

(a) consult with the Society on potential use(s) of Invention and licensees thereof, and specific diligence requirements and/or milestones for inclusion in any license; and

(b) ensure that licensing is for the greater public benefit; and

(c) include provisions in the license to obligate the licensee to commercialize the Invention in a diligent manner, including commercialization for treatment and research relative to FSHD, and to include specific diligence requirements and/or milestones. Such requirements will be determined in accordance with the use(s) of the Invention claimed in the patent application filed on the Invention, as applicable; and

(d) include provisions in the license for termination or conversion to a non-exclusive license as set forth in the following paragraph.

In the event that the licensee has failed to commercialize the Invention in accordance with such diligence provisions, the Grantee Institution shall have the right to either terminate the license or, if the licensee has failed to commercialize the Invention for treatment and research relative to FSHD, convert an exclusive license to a non-exclusive license so that the Grantee Institution may seek other qualified licensees to commercialize the Invention for treatment and research relative to FSHD.

The Grantee Institution will be responsible for monitoring such diligence requirements/milestones. In the event that the licensee has failed to commercialize the Invention in accordance with such due diligence provisions, then at the written request of the Society, the Grantee Institution shall either terminate the license or convert an exclusive license to a non-exclusive license, and shall seek other qualified licensees to commercialize the Invention for treatment and research relative to FSHD.

The Grantee Institution shall provide to the Society copies of the diligence/milestone provisions of any executed license agreement for an Invention, and by February 1 of each year, an annual, confidential report regarding the status of the licensing and/or commercialization of the Invention, including royalties and the licensee's progress against the milestones/diligence requirements. The Society agrees to keep this information in strict confidence and not to disclose it to any third party without the prior written consent of the Grantee Institution, unless (i) disclosure is required by law or by order of any court or other governmental authority or (ii) such information is or becomes publicly available through no fault of the Society.

C. If the Grantee Institution has no established patent policy, the Society shall have the right to determine disposition of the patent rights to arrive at a mutually acceptable resolution in conformity with the Society's policy of bringing the Invention to practical application as expeditiously as possible. The Society may, in such a situation, transfer or license the Invention to a qualified organization or individual for patenting and licensing.

D. From the revenues, if any, received from licensing the Invention, the Grantee Institution, the Grantee and the Society shall share on terms mutually agreed among them. However, the Society's share shall be at least equal to the proportion of funding in support of the Invention that was provided by the Society.

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