



## **Medical and Scientific Research Grant Policies**

### **2017 Eating Disorders Research Grants Program**

The aim of the Klarman Family Foundation's (the "Foundation") Eating Disorders Research Grants Program is to help accelerate progress in and advance understanding of the basic biology behind the clinical phenomena of eating disorders. In developing these Medical and Scientific Research Grant Policies (the "Grant Policies" or "Policies"), the Foundation has considered a wide range of issues relevant to creating the best conditions for research, adhering to best practices in research grantmaking, and ensuring that the outputs of the work that the Foundation funds are managed and shared in ways that maximize public benefit.

The Foundation makes grants to nonprofit academic, medical or research institutions throughout the United States, Canada, and Israel (the "Institution") on behalf of Principal Investigators (the "Grant Recipient") in accordance with the Policies below. The Institution and Grant Recipient are responsible for ensuring all Foundation-funded activities are carried out in accordance with these Policies throughout the grant term ("Funding Period") and for remaining current on Foundation policies as they may change from time to time. Current policies will be made available online at <http://klarmanfoundation.org/eating-disorders-research>.

#### **1. Grant Amount and Funding Period**

One-Year pilot studies of up to \$150,000 USD and three-year grants totaling \$450,000 - \$750,000 USD, inclusive of 10% indirect costs, (each, a "Grant") will be awarded for the Funding Period, which should begin on the first of one of the next four months after Foundation approval of the Grant. Longer delays must be approved by the Foundation. The Foundation may, in exceptional cases, consider proposals with higher budgets and/or longer durations.

#### **2. Management and Use of Grant Funds**

Grant funds will be released according to the provisions and payment schedule in the Grant Agreement between the Foundation, the Grant Recipient, and the Institution (the "Grant Agreement"), and shall be used solely for the purposes specified in the grant proposal and budget submitted to and approved by the Foundation. The Institution is responsible for the administrative and financial management of the grant, including any subcontracts, and maintaining adequate supporting records and receipts of expenditures.

Except as otherwise provided in the Grant Agreement, grant funding may be used to support salaries and fringe benefits, laboratory and data processing supplies, other direct expenses such as equipment and supplies essential to the project, travel to scientific meetings and publication of scientific data. Salaries

must be in proportion to the percentage of effort devoted to the project. Grant funds may not be used for new construction, the renovation of existing facilities, endowments, any lobbying or political activity, or accumulated deficits. Grant funds paid to an Institution located outside the United States may not be used for U.S.-based activities, including travel by personnel to or from the United States, without prior approval by the Foundation.

The Institution must exercise proper stewardship over grant funds and ensure that costs charged to the grant are allowable, allocable, reasonable, necessary, and consistently applied in line with the submitted proposal and budget. The Institution shall be liable for reimbursement to the Foundation of any grant funds associated with any inappropriate or unauthorized expenditures or fraudulent or improper conduct involving the use of grant funds.

### **3. Reporting Requirements**

The Klarman Family Foundation requires scientific and expenditure reports to be submitted at least annually, and according to the specifications and schedule outlined in the Grant Agreement. Final scientific and expenditure reports are due sixty days following the conclusion of the Funding Period. Report forms will be made available on the Foundation's web site or are available upon request from the Grants Manager.

If relevant to the scientific progress of the grant, the progress of each subgrant or subcontract (collectively, "Subcontract") must be included in the scientific reports. A separate scientific report for the Subcontract is not necessary. A separate Subcontract expenditure report for each Subcontract should be submitted along with every expenditure report submitted throughout and at the conclusion of the Funding Period using the template provided.

The Foundation, with reasonable notice to the Institution and Grant Recipient, may request additional reporting, or participation in site visits, telephone conferences, presentations or other speaking engagements.

Reports will be reviewed by Foundation staff and relevant scientific advisors. If any report shows progress to be substantially less than anticipated, the Foundation reserves the right to withhold or redirect any remaining Grant payments. Failure to provide timely and complete reports may result in suspension of the Grant, withholding of payments, early termination of the Grant, and/or reimbursement to the Foundation of any unexpended funds.

### **4. Changes in Grant Status**

Any changes in research design and/or specific aims described in the Grant Recipient's proposal to the Foundation require a formal written request and prior approval before implementation. Changing of research plans without prior approval may result in the suspension of payments, early termination of the Grant, and/or reimbursement to the Foundation of any expended or unexpended funds.

Any change in percent effort of the Grant Recipient, or other personnel providing a substantial intellectual contribution (collectively, the "Key Personnel") requires prior written request and approval. Requests should include the reason for the change and a description of how the change will affect the scope of work, implementation and timeline of the research and/or other Foundation-funded activities. Temporary

leaves of absence of the Grant Recipient or Key Personnel for medical reasons or family obligations will be considered on a case-by-case basis.

All requests for changes to the research design, aims, or percent effort of the Grant Recipient or Key Personnel must be received by the Foundation at least 60 days prior to the desired effective date of the change.

If the Grant Recipient is planning a move to another nonprofit research institution during the Funding Period, transfer of funds to continue the project must be requested in writing to the Grants Manager as soon as practicable. The request must include an expenditure report stating the remaining fund balance and a letter from the future department chair confirming the availability of resources to continue the project. If the transfer is approved, the Grant Recipient will be responsible for notifying the Foundation of the new payee institution and coordinating the funds transfer. If the research will not be continued at another nonprofit research setting, the Grant will be cancelled and unused funds must be returned to the Foundation within 60 days. Disposition of any equipment purchased with Grant funds will be evaluated on a case-by-case basis. Transfer of the Grant to another principal investigator is not permitted.

It is the responsibility of the Grant Recipient and the Institution to notify the Foundation of any change in employment status of the Grant Recipient at least 30 days prior to such change, provided that the Grant Recipient and Institution have advance notice of such change.

## **5. Ethical Issues**

The highest scientific and ethical standards in the conduct of research supported by the Foundation must be maintained at all times. All involved parties agree to abide by all applicable national/federal, state and local standards relating to research integrity, research misconduct, and research with humans and animals.

Research involving animals will conform with the current National Institutes of Health (NIH) publication *Guide for the Care and Use of Laboratory Animals*, U.S. Department of Health and Human Services (DHHS)/U.S. Public Health Service (PHS) standards, the current PHS policy on animal research, federal, state and local laws and regulations, and be approved and monitored by the Institution's Animal Care and Use Committee (IACUC) or equivalent throughout the Funding Period. Grant funds may not be used for research involving laboratory animals until IACUC certification of approval, identifying the Institution, Grant Recipient, project, and relevant Key Personnel, has been submitted to the Foundation. Any significant deviation from the applicable laws, regulations and standards in the conduct of research with animals funded by the Foundation must be promptly reported to the Foundation by the Institution.

Research involving human subjects will conform with the requirements of 45 C.F.R. Part 46 and any other applicable national, state and local laws and regulations, including, unless otherwise allowed by applicable laws and regulations, the provision of suitable explanation to subjects or their guardians concerning the experimental design and all significant hazards, so that they may be in a position to provide appropriate informed consent prior to the investigation. All research involving human subjects must be reviewed, approved in writing, and be continually monitored throughout the Funding Period by a cognizant Institutional Review Board (IRB), constituted in accordance with applicable law and regulations and consistent with the standards set forth in 45 C.F.R. Part 46. The Institution bears ultimate responsibility for protecting human subjects under the Grant, including human subjects at any other

collaborating site as a part of the Grant. Grant funds may not be used for research involving human subjects until IRB certification of approval, identifying the Institution, Grant Recipient, project, and relevant Key Personnel, has been submitted to the Foundation. Any significant deviation from the applicable laws, regulations and standards in the conduct of research with humans funded by the Foundation must be promptly reported to the Foundation by the Institution.

In regard to research misconduct, the Institution must, at all times during the Funding Period, have in place guidelines and procedures consistent with 45 C.F.R. Part 93 and with any other applicable laws and regulations. In the unlikely event that a party involved in Grant-funded activities is involved in an investigation of scientific and/or financial misconduct, he or she will be subject to the procedures in place at the Institution. As soon as practicable after the initiation of any research misconduct fact-finding or procedure, the Institution must notify the Foundation in writing of both the investigation and the procedures that the Institution will follow. A finding of scientific and/or financial misconduct must be promptly reported to the Foundation and may affect the Grant Recipient's continued eligibility for funding.

Institutions are required to promptly report to the Foundation any disclosures made by the Grant Recipient or Key Personnel involved in a Grant-funded activity regarding a possible financial or other conflict of interest. Depending on the nature of the conflict of interest the Foundation may request that the Grant Recipient or Key Personnel sign a separate form of acknowledgment.

## **6. Indirect Costs**

Indirect costs should be kept to a minimum, and may not exceed 10% of direct costs, unless specified otherwise in an award letter or the Grant Agreement. Indirect costs include: facilities costs, such as depreciation and use allowances, interest on debt associated with certain buildings, equipment and capital improvements, operation and maintenance expenses and library expenses; and administrative costs, such as general administration and general expenses, departmental administration, sponsored projects administration, and student administration and services. Indirect costs may not be charged on equipment.

Indirect costs may not be charged on Subcontracts which include indirect costs. Indirect costs paid to a subcontractor may not exceed 10% of the direct costs paid to the subcontractor.

## **7. Reallocation of Grant Funds**

Expenditures are expected to be within a reasonable range of the budget that was submitted with the Grant proposal, but may be reallocated within existing, approved budget categories if necessary and in line with the approved project scope. The following types of requests for reallocation of funds require the Grant Recipient to obtain prior written approval from the Foundation and complete a written form (the "Budget Reallocation Request Form"): (1) requests for reallocation of any amount within the personnel budget category and (2) requests for reallocations in categories other than personnel of amounts equal to or in excess of \$50,000 or 15% of the total Grant amount budgeted for the year, whichever is less. Budget Reallocation Request Forms are available upon request from the Grants Manager. Amounts of less than \$50,000 or 15% of the total Grant amount budgeted for the year, whichever is less, may be reallocated within a budget category (except within the personnel category) without prior written permission, but shall immediately be reported to the Foundation with a revised budget.

In the unusual case of needing to reallocate among, rather than within, approved budget categories, the Budget Reallocation Request Form is required regardless of dollar amount.

## **8. Carry Forward of Grant Funds**

If applicable, a Grant Recipient may carry forward unexpended Grant funds from one funding year to the next. A carry forward of an amount in excess of the lesser of \$50,000 or 15% of the Grant amount budgeted for that year or more requires a formal request and prior written approval. Requests must be made using the Carry Forward of Grant Funds Request Form which is available upon request from the Grants Manager. Requests are due 30 days prior to the end of the funding year. Amounts less than \$50,000 or 15% (whichever is less) of the Grant amount budgeted for that year may be carried forward without prior authorization. The Foundation may, at its discretion, alter the Grant payment schedule in the case of a significant carry forward. Please note that an approved carry forward does not guarantee an approved no-cost extension at the end of the Funding Period. Please see the No-Cost Extensions section for further information.

## **9. No-Cost Extensions**

The Grant Recipient may request a one-time no-cost extension of up to 12 months to extend the end date of a Grant without the Foundation providing additional funding. The request must use the No-Cost Extension Request Form which is available upon request from the Grants Manager. The plan for continued use of Grant funds must adhere to the previously approved objectives of the project; an expansion of Grant objectives or additional aims will not be considered. Grant Recipients are cautioned not to make new commitments or incur new expenditures after the expiration date in anticipation of a no-cost extension. The presence of unobligated funds at the end of the Funding Period is not in itself sufficient justification for an extension.

Requests should be received no earlier than 90 days or later than 30 days prior to the end of the Funding Period. Any funds remaining at the close of the extended (if approved) or original (if declined) Funding Period must be returned to the Foundation within 60 days.

## **10. Other Funding**

Neither the Institution nor the Grant Recipient will accept funding from another source which will result in an overlap of funding for the Grant-funded project or result in greater than 100% effort of the Grant Recipient or Key Personnel. The Institution and the Grant Recipient are responsible for determining whether acceptance of this Grant will jeopardize support they may receive from other sources, and ensuring that the Grant Recipient has the capacity required to perform the research within the proposed timeline. Additional funding for activities related to this Grant shall be reported to the Foundation immediately.

## **11. Confidentiality**

The Foundation consults with a variety of third-party scientific advisors from both academia and industry, who are recognized as leading experts in their fields. These advisors provide scientific review of research proposals and reports to ensure that Grant-funded research is scientifically sound, pertinent and in line with the mission and goals of the Foundation.

Except where otherwise specified, application materials, evaluations, priority scores, and interim/final scientific and expenditure reports will be deemed Confidential Information and will not be disclosed by the Foundation, except to the Foundation's scientific advisors, trustees and staff (collectively, the "Foundation Representatives") as part of the application, review and monitoring processes. The Foundation will require all Foundation Representatives to sign a confidentiality agreement, but will be held harmless in the event any Foundation Representative breaches such confidentiality agreement. The Institution and/or the Grant Recipient may receive or have access to confidential information of the Foundation in connection with the Grant. Neither the Institution nor the Grant Recipient will disclose the Foundation's confidential information, including without limitation the terms of the Grant or Grant Agreement, to any third party without prior written consent from the Foundation.

## **12. Liability and Insurance**

The Foundation or its officers, directors, employees or scientific advisors are not responsible for any claim, judgment, award, damages, settlement, negligence or malpractice arising from any Grant-funded activities. The Institution acknowledges responsibility for the conduct of activities, research and investigations related to this Grant, and releases the Foundation from all claims and/or liability that may arise from any act or omission on the part of the Institution, Grant Recipient, its employees, agents, or representatives to the extent allowed by applicable law.

The Institution shall maintain adequate liability and property insurance in sufficient amounts to cover actionable legal claims for liability or loss which are the result of injury to or death of any person, damage to property caused by the negligent acts or omissions, or negligent conduct related to the Grant. Insurance should cover the Grant Recipient(s), employees, officers, and agents of the Institution for the duration of the Grant. The Foundation may request to be provided certificates evidencing the insurance coverage at any time during the Funding Period.

## **13. Record Keeping and Audit**

The Institution will keep systematic records, in a manner consistent with generally accepted accounting principles, of all expenditures directly or indirectly relating to the Grant. Vouchers consisting of bills, invoices, cancelled checks, receipts, and other data, as appropriate, will be retained by the Institution for seven (7) years after the close of the Funding Period. Records will be available for inspection by representatives of the Foundation during normal business hours and upon reasonable notice throughout the Funding Period and the subsequent record retention period. The Foundation may, at its own expense, perform site visits, examine, audit, or have audited the records of the Institution insofar as they relate to activities supported by the Grant. Failure to comply or produce expenditure records as requested shall entitle the Foundation to withhold Grant payments until such compliance is demonstrated.

The Foundation also has the right to request and receive from the Institution or Grant Recipient, or review during a site visit, copies of all research records relating to the Grant at any time during or after the Funding Period for up to seven (7) years following the submission of the final scientific and expenditure reports. Research records are materials that document the research effort for laboratory research, animal or human subject research and/or clinical trial research. These may be electronic or hard copy, and include, but not limited to: logs, notebooks, correspondence, libraries, videos, computer databases or records, audio or digital records relating to Grant-funded activities.

## **14. Intellectual Property**

Subject to the licenses described herein and the requirements of Section 15 “Public Access,” the Institution will own (to the extent protectable by applicable law) any and all discoveries, inventions, methods, processes, designs, protocols, computational algorithms, creations, developments, works of authorship or other work product made, conceived or reduced to practice in the performance of research supported, in whole or in part, by the Grant (collectively, the “Inventions”), and any and all worldwide proprietary rights in or to such Inventions, including patent rights, copyrights and other intellectual property rights (collectively, the “Intellectual Property Rights”). The Institution will require all employees and consultants involved in any research supported, in whole or in part, by the Foundation to assign in writing all Intellectual Property Rights they have in and to the Invention to the Institution.

The Institution must notify the Foundation in writing of the following: (i) any and all Inventions, promptly after the making, conception or reduction to practice of such Inventions, but in any event no later than the time a disclosure related to the Invention has been received by or filed within the Institution and (ii) the filing of any United States or foreign patent application or the issuance of any United States or foreign patent that includes, incorporates, uses or claims any Invention, or the filing of any other application or any other issuance or approval related to any other Intellectual Property Rights in any Invention (such worldwide patent and other Intellectual Property Rights applications and the resulting registered rights, collectively, “Applications”), not later than 30 days after any such filing, issuance or approval, including in such notice a copy of such filing, issuance or approval. The Institution must provide the Foundation with reasonable updates concerning the status and progress of all Applications. The Institution will be solely responsible for all costs and expenses related to the filing, prosecution, and maintenance of such Applications.

The Institution will not abandon or fail to maintain any Application without prior written notice to and consent of the Foundation. The Institution must provide the Foundation with such notice at least sixty (60) days prior to any such abandonment. In the event of such notice, the Foundation will have the right to take title to the applicable Invention and prosecute and maintain the Application at the Foundation’s expense. In addition, the Foundation will have the right to take title to an Invention and, at the Foundation’s expense, file and prosecute Applications in any country where the Institution has failed to file such an Application within six (6) months after notification of the applicable Invention to the Foundation. Upon the Foundation’s request and at the Foundation’s expense, the Institution will provide powers of attorney and other documents and take such other actions necessary for the Foundation to exercise its rights in any Invention or Application as provided herein.

The Institution will endeavor and will cause its licensees to endeavor in good faith to bring each Invention to the point of practical application promptly after notice of such Invention to the Foundation. For purposes of these guidelines, the term “practical application” means the manufacture, use, operation, sale, distribution, or other appropriate practice of an Invention under such conditions as to establish that such Invention is being utilized and that its benefits are, to the extent allowable by federal and state law and regulations, available to the public on reasonable terms. If the Institution or its licensee fails to bring an Invention to practical application within three years after a U.S. patent issues on such Invention or within such other timeframe as the Foundation and Institution agree upon, and the Foundation identifies a suitable candidate interested in commercializing the Invention, the Institution will consider such

candidate as a potential licensee and will license the Invention to such candidate, provided that the terms of such license are reasonably acceptable to the Institution. In the event the Foundation has not identified a suitable candidate for commercializing the Invention and the Grantee Institution or its licensee have not brought the Invention to practical application within three years after a U.S. patent issues on such Invention or within such other timeframe as the Foundation and Institution agree upon, then the parties will discuss the alternative disposition of rights in the Invention including, but not limited to, the assignment of any related patent rights or other Intellectual Property Right to the Foundation or its designee and the cancellation of any outstanding exclusive license agreements.

To allow time for the Grant Recipient and/or Key Personnel to publish research findings or submit a patent or other application for Intellectual Property Rights, the Foundation agrees to a one-year waiting period following the earlier of (i) the date that the disclosure of the Invention was received by or filed within the Institution, or (ii) the end date of the Funding Period. Thereafter, the Institution will make information regarding the Inventions available to the Foundation, to other researchers working at nonprofit organizations as reasonably requested by the Foundation, and to any other researchers working at nonprofit organizations who otherwise request access thereto from the Institution, without charge (except that the Institution may request reimbursement for its preparation and shipping costs) for teaching, research and other non-commercial purposes. Such information must be sufficient to enable the Foundation or such researchers to make practical use of such Inventions, as determined by the Foundation's Scientific Advisors. Accordingly, effective upon the first anniversary of the end of the Funding Period, the Institution agrees to grant to the Foundation and each such nonprofit organization (each, a "Licensee") a non-exclusive, worldwide, irrevocable, perpetual, fully-paid up, royalty free license, with the right to sublicense to affiliates, license partners, collaborators and contractors of the Licensee (collectively, the "Authorized Users") through multiple tiers, under the Intellectual Property Rights in order to make and use Inventions, including without limitation creating derivative works thereof, for teaching, research and other non-commercial purposes (each, a "Research License"). The Foundation will not assume any liability or responsibility whatsoever with respect to any such Research Licenses. The Institution may require researchers or entities seeking to obtain a Research License to enter into a formal license agreement with the Institution, provided that the terms of such license agreements are no more restrictive than those that apply to the Foundation.

The Institution may not assign or sell any Inventions (or any Intellectual Property Rights therein or thereto) or grant any income-generating license under Intellectual Property Rights, without first giving the Foundation written notice at least 30 days prior to the action, including in such notice a copy of any assignment or sale document or license agreement. Any such assignment or sale of Intellectual Property Rights or granting of any such license will be subject to the Research Licenses.

Notwithstanding the foregoing, the Institution and the Foundation agree that an exclusive license under the Intellectual Property Rights may be granted by the Institution if, and only if, the granting of such is, as determined upon mutual agreement by the Institution and the Foundation, reasonably likely to: (i) maximize the positive impact of the Inventions on the health of individuals; (ii) maximize the availability of diagnostic or therapeutic products to individuals; or (iii) maximize the speed at which diagnostic or therapeutic products are available to individuals.



The Foundation intends and the Institution agrees that no provision of these Policies, or of any other document related to the Grant, and no course of dealing between the Foundation and the Institution shall constitute or be deemed to constitute a partnership, joint venture or similar arrangement.

## **15. Public Access**

Grant Recipients conducting biomedical research frequently develop unique research resources. The sharing of such unique research resources is essential for expedited translation of research results into knowledge, products and procedures to improve human health. Therefore, the Grant Recipient accepts the responsibility of providing research resources developed during the course of the Grant when reasonably requested to do so. The Grant Recipient agrees to share all resources, data, samples, information, discoveries, or ideas arising out of research funded in whole or in part by the Foundation with the Foundation and the medical and scientific community at large, in accordance with the proposed data and resource sharing plan (the “Dissemination Plan”) as approved by the Foundation. As the community standard for early data release is evolving, the Grant Recipient’s Dissemination Plan may be reassessed throughout the Funding Period. The Grant Recipient and/or Key Personnel will endeavor to publish all findings in peer-reviewed journals as soon as possible and provide all supporting data to the public domain. The Foundation strongly encourages the posting of preprints on recognized servers in parallel with (or even before) submission to a peer-reviewed journal.

The Grant Recipient shall make every effort to deposit all data collected and generated through Foundation-funded activities into public databases (e.g., NIH Data Sharing Repositories) that are widely accessible, without charge, to the scientific research community. If no such databases are available that properly fit the type and content of the research-generated data, the Grant Recipient shall make every effort to make these data available through electronic supplementary tables and figures associated with publications.

Any embargo on the use of data by researchers who were not supported by the Grant should be a publication embargo, not an access embargo. This publication embargo will not exceed one year after deposit into the relevant databases/repositories. This provision survives the conclusion of the Funding Period.

## **16. Early Termination of Grant**

Should any of the following events occur, The Foundation has the right to terminate the Grant immediately, and may demand repayment of all unexpended Grant funds and any remaining Grant payments may be cancelled:

- The Institution or Grant Recipient fail to perform any of their duties as required by the Grant Agreement or these Policies, in the sole discretion of the Foundation or its scientific advisors;
- The Institution or Grant Recipient are debarred from the receipt of federal or state funding;
- A determination, preliminary or otherwise, is made by the United States Internal Revenue Service that the Grant constitutes a taxable expenditure as defined in section 4945(d) of the Internal Revenue Code of 1986, as amended (the “Code”)

- The Institution ceases to be a nonprofit academic, medical or research institution.

Typically, the Foundation will allow the Institution and/or the Grant Recipient to take corrective measures should the possibility of termination arise from financial, ethical, administrative or programmatic insufficiencies. In such cases, the Grant will be suspended until corrective actions are taken as outlined by the Foundation.

All early terminations require the submission of final scientific and expenditure reports and a check for any unexpended funds, to be received within 60 days of the termination.

Any provision of these Policies which the parties have agreed will expressly survive or by their nature should survive termination of the Grant or the expiration of the Funding Period, will continue to survive after the termination of the Grant or the expiration of the Funding Period, including, but not limited to Sections 13 (Record Keeping and Audit), 14 (Intellectual Property), 15 (Public Access) and 17 (Post Award Reporting).

### **17. Post Award Reporting**

The Grant Recipient will respond to the Foundation's requests for information on research progress following the Funding Period and may be requested to provide a current Curriculum Vita or update information in an online database. The Grant Recipient understands that this obligation survives the Funding Period.

### **18. Scientific Meetings and Events**

During the Funding Period, the Grant Recipient may be asked to present a summary of his/her research progress at scientific meetings, including Foundation-hosted meetings in Boston, MA. Reasonable travel and overnight expenses will be reimbursed for Foundation-requested travel beyond the monitoring and budget of the current Grant Grant Recipients are also expected to share research findings in a timely manner through professional meetings and/or publications.

### **Contact**

Please contact Erin Peterson, Grants Manager at [EDresearch@klarmanfoundation.org](mailto:EDresearch@klarmanfoundation.org) for any questions relating to these Policies, requests for reallocations, carry-forwards, no cost extensions, report templates and/or submissions, or any other pre- or post-Grant inquiries.