

American Diabetes Association

Research Programs

Effective for new Awards as of January 2015

Stipulations Governing Research Grants

<u>diabetes.org/qrants-admin</u> <u>grantadministration@diabetes.orq</u>

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Our Mission is to prevent and cure diabetes and to improve the lives of all people affected by diabetes.

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I. General Provisions

A. Award Communications

All requests and communications regarding the administration of Association-funded Grants (e.g. Institutional Transfers, No-Cost Extensions, Carryover Requests, Patent Report, etc.) must be made in writing to American Diabetes Association ("Association") Research Programs staff at grantadministration@diabetes.org, and must include the appropriate supporting documentation utilizing current templates and forms provided at diabetes.org/grants-admin.

Grantee and Grantee Institution shall respond to payment and/or administrative inquiries (such as requests for photos, annual Progress or cumulative Final Reports, CV's, etc.) from the Association in a timely fashion. Grantee or Grantee Institution's failure to respond to such inquiries for more than six (6) months is grounds for Grant termination for non-compliance with Grant terms.

B. Research Profile

Grantee must complete a Research Profile, consisting of a lay description of the supported research project and a digital photograph of the Grantee working in a laboratory or clinical setting. Research Profile content may be used in the Association's annual Research Report, monthly Research Updates, online Research Database, on the Association's website(s) and/or in other hardcopy or online publications. The Research Profile may additionally be used as the basis for press releases and possible feature stories in future Association publications.

C. Professional Membership in the American Diabetes Association

Grantee is required to be a current professional member of the Association during the Grant Period. Professional Membership information is available online at <u>diabetes.org/pro</u>. Membership fees cannot be paid with Grant Funds.

D. Information Made Available to the Public

The Association may include Grantee and Grant information (e.g. name, degrees, Grantee Institution, project title, Grant amount, lay abstract) in electronic and printed materials, such as its Grantee directory and other publicly accessible databases of privately funded grant awards. The Association reserves the right to include information relating to the Grant in the Association's periodic reports, newsletters, news releases or any other materials issued by or on behalf of the Association. Grantee shall avoid disclosing confidential information in lay abstract and summaries provided to the Association and mark any confidential materials as such prior to submission to the Association. This provision shall survive expiration or termination of the Grant.

Grantee and Grantee Institution agree to use reasonable efforts to make themselves available, to make presentations about their research to Association volunteers, staff and potential donors, or for a ceremonial presentation of the Grant Award at the beginning of the project or during subsequent years of funding, if requested by the Association.

E. Acknowledgement of Association Support

Grantee and Grantee Institution shall acknowledge support from the American Diabetes Association when findings are reported or publicity is given to the research and in all research publications arising in whole or in part from Association Grant Funds. Publication acknowledgement must include the following language: **"Supported by American Diabetes Association Grant XX-XX-XXX-XXX."** Copies of all publications resulting from Association-supported research must be sent to Association staff at grantadministration@diabetes.org.

F. Use of Logos and Trademarks

Except as expressly provided in the Grant, Grantee and Grantee Institution will not use the name, trademarks, logos, symbols or other images of the Association without the Association's prior written consent. This provision shall survive expiration or termination of the Grant.

II. Award Administration

A. Award Agreement

The Award Letter serves as the agreement between the Grantee, Grantee Institution and the Association regarding the conferral and acceptance of an Association Grant. Issuance of Award Letter is subject to Grantee's timely filing of pre-award requirements. Failure to file pre-award requirements in a timely manner, or to adequately address administrative concerns, may result in reduction(s), revocation, suspension or termination of the Grant at the Association's sole discretion. Funding approval for subsequent years is renewed on a yearly basis.

B. Renewals

Renewal Letters are issued on an annual basis and are subject to Grantee's timely filing of Progress Reports. Failure to timely file an annual Progress Report, or to demonstrate adequate research or financial progress as determined by Association staff, may result in reduction(s), nonrenewal, suspension or termination of the Grant, at the Association's sole discretion.

C. Right of Assignment

All Grant Funds will be made payable to the Grantee Institution, but are specifically assigned to the named Principal Investigator and are transferable (with the Principal Investigator) between institutions. The Grant may not be otherwise assigned by Grantee or Grantee Institution without the prior written approval of the Association. If the Grantee or Grantee Institution assigns the Grant without prior written approval from the Association, the Association at its sole discretion may terminate the Grant immediately without further notice and the Association will not be obligated to provide any further Grant Funds to Grantee or Grantee Institution.

D. Institutional Transfers

Grantee shall not transfer Grant Funds between Grantee Institutions without the prior written authorization of the Association. If a Grantee wishes to transfer a Grant from one Grantee Institution to another (the "prospective Grantee Institution"), Grantee shall notify Association in writing of the intended date of transfer (the "Transfer Date"). The Association shall not be obligated to provide Grantee or any current or prospective Grantee Institution with any payments of Grant Funds on or after the date of the notice of transfer until the Association has received written confirmation that all financial and administrative matters have been completed at each respective Grantee Institution, and the prospective Grantee Institution agrees in writing to be bound by the terms and conditions of the Award Letter including its attachments. For further information regarding the transfer process and required forms/templates, refer to the Research Programs website at <u>diabetes.org/grants-admin</u>.

In the event of transfer, a Final Financial Reconciliation covering the work performed up to the Transfer Date must be submitted to the Association within sixty (60) days after the Transfer Date by the initial Grantee Institution ("Transferor") to close out the account. Any and all adjustments must be incorporated into the final reconciliation and accounting in the Final Financial Reconciliation. Any claims by Grantee or Transferor for reimbursement of any expenses, fees or costs incurred by Grantee or Transferor in accordance with the Grant prior to the Transfer Date that are not submitted to the Association within sixty (60) days after the Transfer Date shall be deemed waived and the Association shall not be obligated to reimburse the Grantee or Transferor for any such expenses, fees or costs. If the Association reimburses the Grantee or Transferor for expenses, fees or costs incurred by Grantee or Transferor in accordance with the Grant prior to the Transfer for any such expenses, fees or costs. If the Association reimburses the Grantee or Transferor for expenses, fees or costs incurred by Grantee or Transferor in accordance with the Grant prior to the Transfer Date, such reimbursement will be deducted by the Association from the next scheduled payment to be paid to the prospective Grantee Institution and remitted to the Transferor.

Awards in the process of transferring will be placed on hold and will not receive further payment until the Association has issued written confirmation that all financial and administrative matters have been completed at each respective Grantee Institution.

E. Fellow Changes (Mentor-Based Training Awards)

Fellow changes are permitted throughout the duration of Mentor-Based Training Awards. If the Fellow vacates the position and a new Fellow (the "prospective Fellow") cannot be readily appointed, the Award will be placed on hold until a Fellow is officially designated and approved by the Association. The prospective Fellow must meet all eligibility criteria for the Award, refer to the Application Instructions for specific requirements. In the event of change of Fellow, the Principal Investigator (i.e., Mentor) must submit all required documentation to the Association for review and approval prior to the prospective Fellow beginning work on the Award. If the Association is not notified of a vacant Fellow position, the Grant may be reduced by the total amount distributed during the Fellowship vacancy period.

F. Budget Revisions

Once the Award Acceptance Agreement has been executed by the Grantee and Grantee Institution and submitted to the Association, budget revisions greater than twenty-five percent (>25%) in any budget category set forth in the approved Grant budget (including, without limitation, Principal Investigator salary, Technical Personnel, Supplies, Equipment and Other) must be approved by the Association. Requests must be submitted in writing and Grantee shall not implement changes in any budget category without prior written authorization by the Association. Notwithstanding the foregoing, written approval is not required if the budget revision is less than twenty-five percent (<25%) in each budget category, however a revised budget form must be submitted by email to grantadministration@diabetes.org.

G. Funding Carryover

Grant Funds exceeding twenty-five dollars (>\$25) that have not been expended in accordance with the Grant as of close of the Award year may be carried over to the following year upon review and approval by the Association. In the event of Grant Fund carryover, Grantee and Grantee Institution must complete the carryover justification section(s) of the annual Progress Report and submit to the Association by the Progress Report due date. Carryover funding is determined on a case-by-case basis.

H. No-Cost Extensions

A request for a single No-Cost Extension (six months or one year) may be considered upon prior written request to the Association. The request and required documentation must be received at least two months prior to the stated Grant End Date. Only one request for a No-Cost Extension will be considered per Grant, subsequent requests for extension will not be accepted.

I. Award Relinquishment

Grantee may relinquish, i.e., terminate, the Grant for any reason upon prior written notice to the Association. In the event of relinquishment, pending Grant Funds that may be owed to the Grantee or Grantee Institution will be pro-rated based on the number of days remaining in the applicable payment cycle up to the date of relinquishment (the "Relinquishment Date"). The commitment of Grant Fund payments to the Grantee Institution for the remainder of the Grant Period after the Relinquishment Date is automatically null and void. The Relinquishment Date stated in writing by the Grantee Institution shall return to the Association all Grant Funds exceeding twenty-five dollars (>\$25) that have not been expended in accordance with the Grant as of the Relinquishment Date. This provision shall survive expiration or termination of the Grant.

J. Right to Terminate

The Association reserves the right to terminate the Grant for noncompliance with its terms and conditions, including these Grant Stipulations and the Association's policies and guidelines, which are located at <u>diabetes.org/grants</u>, upon ninety (90) days written notice to the Grantee and Grantee Institution. The Association will not be obligated to provide any further Grant Funds to Grantee or Grantee Institution after the date of the notice of termination, however, the Association will reimburse the Grantee Institution for fees, costs and non-cancellable obligations incurred in accordance with the Grant prior to the date of the notice of termination, provided such fees, costs, and non-cancellable obligations are supported by sufficient evidentiary documentation. Any claims

by Grantee or Grantee Institution for reimbursement of such fees, costs and non-cancellable obligations that are not submitted to the Association within six (6) months after the date of the notice of termination shall be deemed waived and the Association shall not be obligated to provide any reimbursement for such fees, costs, and non-cancellable obligations. This provision shall survive termination of the Grant.

The Association also reserves the right to terminate the Grant for any other reason upon ninety (90) days written notice to the Grantee and Grantee Institution and the Association will not be obligated to provide any further Grant Funds to Grantee or Grantee Institution. Notwithstanding the forgoing, if a Grant is terminated by the Association for any reason other than non-compliance with its terms and conditions, the Association will reimburse the Grantee Institution for fees, costs and non-cancellable obligations that that were incurred in accordance with the Grant up to the effective date of termination, or through the end of the then current Award year, whichever date is earlier. Any claims by Grantee or Grantee Institution for reimbursement of such expenses, fees and costs that are not submitted to the Association within six (6) months after the date of the notice of termination shall be deemed waived and the Association shall not be obligated to provide any reimbursement for such expenses, fees and costs. This provision shall survive termination of the Grant.

III. Reporting Requirements

A. Progress Reports (Annual)

Grantee must submit a complete annual Scientific Report and Financial Reconciliation (collectively, "Progress Report"). Forms for preparing the reports can be found at <u>diabetes.org/grants-admin</u>. The Financial Reconciliation must be co-signed by the Grantee and the Grantee Institution's fiscal office. Progress Reports are considered transaction records/history for the Grant. By submitting a signed report, Grantee and Grantee Institution acknowledge the receipt and expense of Grant Funds for the reported Grant Period. Copies of publications resulting from Association support must be provided with the subsequent Progress Report.

Failure to demonstrate adequate research or financial progress as determined by Association staff, may result in reduction(s), nonrenewal, suspension or termination of the Grant at the Association's sole discretion. The Association reserves the right to reduce Grant Funds by five percent (5%) for any year of the Grant in which a required Progress Report is not received on or before the respective due date(s). Any reduction amount shall be deducted from the next scheduled payment(s). Should an annual Progress Report not be received and deemed complete by the Association within ninety (90) days after its due date, the Grant may be terminated immediately by the Association without further notice.

B. Final Report (Cumulative)

At the close of the Grant, Grantee must submit a complete cumulative Final Report, consisting of a Final Scientific Report and a Final Financial Reconciliation, within sixty (60) days after the earlier of (i) the Grant End Date as defined in the Award Letter or (ii) the Termination Date of the Grant, if the Grant is terminated prematurely. The Final Financial Reconciliation must cover the entire Grant Period as defined in the original Award Letter, in addition to any No-Cost Extension of the Grant Period, and must be co-signed by the Grantee and Grantee Institution's fiscal office. Any and all adjustments must be incorporated into the final reconciliation and accounting set forth in the

cumulative Final Financial Reconciliation. Within sixty (60) days after the Grant End Date, Grantee Institution shall return to the Association all Grant Funds exceeding twenty-five dollars (>\$25) that have not been expended in accordance with the Grant as of the Grant End Date. These provisions shall survive expiration or termination of the Grant.

If the complete Final Report is not received and deemed complete by the Association as of the due date, (i) the Grantee will not be awarded and will not be eligible to apply for any additional Association Grants until the cumulative Final Report is received and deemed complete by the Association, and (ii) the Association may at its sole discretion suspend payment of any or all of Grantee's existing Association Grant(s) (if applicable) until the cumulative Final Report is received and deemed complete by the Association.

C. Patent Reporting

All inventions made with the support, in whole or in part, of Grant Funds must be reported in accordance with the Association's Intellectual Property Policy (see Section V).

D. Program Assessment

Grantee agrees to participate in follow-up assessments of his/her scientific and professional progress. For a period of five (5) years after the Grant End Date and in response to a request from the Association, Grantee will annually inform the Association of his/her professional status, research support and publications in order for the Association to assess the effectiveness and impact of Grant Funds. This provision shall survive expiration or termination of the Grant.

IV. Financial Stipulations

A. Award Budget Terms

Under no circumstances will the budget for a Grant be increased beyond the original amount set forth in the Award Letter. Investigative work proposed is expected to be completed by the end of the Award term. In the event the Research Project is not completed within the allotted time, Grantee and Grantee Institution will be required to return remaining Grant Funds to the Association. Any Grant Funds exceeding twenty-five dollars (>\$25) that have not been expended in accordance with the Grant as of the Grant End Date must be returned to the Association. The Association reserves the right to reduce Grant budgets at its sole discretion.

B. Use of Funds

All Grant Funds set forth in the Award Letter shall be used solely for the Research Project. Principal Investigator salary allocation shall be in accordance with Grantee's percent effort on the Project and be within allowable salary guidelines as stated in the Application Instructions. Grant Funds may not be used for internet or telephone service support, computer hardware or other smart devices, rent for office or lab space, custodial or administrative support, tuition, relocation costs, memberships or subscriptions. Specific budget stipulations vary per Grant, refer to the Budget Guidelines section of the Application Instructions for allowable budget allocations.

C. Record Maintenance

Grantee Institution shall maintain adequate books and records to track and substantiate expenditure of Grant Funds. All expenditures of Grant Funds must be made in furtherance of the purposes of the Grant and shall appear on those books and records. Upon request by Association, Grantee Institution shall make all such books and records available to the Association or its designee for review and audit at reasonable times during normal business hours and upon reasonable notice.

D. Overlapping Funding

The Association does not permit duplicate or overlapping funding for Grant aims or projects that are concurrently supported by another funding source. Potential overlapping funding from other funding sources must be reported to the Association immediately for evaluation and remediation.

(1) Overlapping Project Support

An overlap of funds shall mean any funds that support the same Research Project as Association Grant Funds. In cases of scientific and/or budgetary overlap, overlapping Grant Funds must be returned to the Association as of the commencement date of the overlapping project support.

(2) Awards of Similar Intent (Training and Development Awards)

For Training and Development Awards, an overlap of funds may additionally be defined to include awards of similar intent (e.g., NIH K awards, other career development awards). In instances of overlapping Training or Development awards, Grantee must relinquish one of the awards.

E. Equipment Purchases

The Association defines equipment as a non-consumable that costs more than \$5,000 and has a lifespan of two or more years. All equipment purchases must be itemized and require prior written approval from the Association if not included in the original approved budget. Equipment purchases are not permitted in the final year of the Award. Equipment purchased with Association Grant Funds is for the use of the Grantee and collaborators for the Research Project. Unless otherwise agreed in writing, title to equipment will be vested in the Grantee Institution. It is agreed that title to the equipment shall also be transferred to the prospective Grantee Institution in the event of Grant transfer. Grantee and Grantee Institution agree, in compliance with the Internal Revenue Code of 1986, as amended (the "Code"), all equipment purchased with Grant Funds shall be used exclusively for charitable purposes consistent with the tax-exempt purposes of the Association and Grantee Institution.

V. Intellectual Property Rights

In consideration of the Grant, Grantee Institution and Grantee both agree to the terms of the Association's Intellectual Property Policy ("IP Policy").

VI. Professional Standards & Legal Compliance

Grantee and Grantee Institution agree that the Grantee Institution and all persons participating in the Research Project will conduct said Research Project in accordance with generally accepted professional standards and obey all applicable laws, ordinances, rules, regulations, requirements and orders of all municipal, county, state or federal authorities or agencies. This includes agreement to comply with all Association and Institutional policies including but not limited to animal use and welfare, human subjects, and scientific and financial misconduct.

A. Responsible Use of Animals in Research

Grantee is responsible for providing humane care for vertebrate animals used in all research supported by Grant Funds in whole or part, and obtaining documented review and approval from a formally constituted Institutional Animal Care and Use Committee (IACUC) or equivalent institutional review body prior to initiating research involving vertebrate animals. The Association requires assurances of the responsible use of animals by requiring the following:

- 1) Grantee Institution must meet standards of the U.S. Public Health Service (PHS), or equivalent, as outlined in the Policy on Humane Care and Use of Laboratory Animals, referenced at the following link: grants.nih.gov/grants/olaw/references/phspol.htm.
- 2) To certify that the animal facilities, including staffing, meet appropriate standards, verifiable assurances of IACUC approval must be submitted to the Association in writing before final approval of Grant funding, and annually throughout the Grant Period for approval of continuing funding.

The Principal Investigator and Grantee Institution have the ultimate responsibility for the conduct of research, including the appropriate care and management of animals throughout the course of the experiments.

B. Human Subjects in Research

Grantee is responsible for guaranteeing the rights, safety and wellbeing of human subjects in all research supported in whole or in part by Grant Funds, and obtaining documented review and approval from a formally constituted Institutional Review Board (IRB) or equivalent institutional review body prior to initiating studies involving people, medical records and human tissues. The Association requires assurances of the protection of human subjects by requiring the following:

- 1) Grantee Institution must meet guidelines of the U.S. Department of Health and Human Services (HHS) and U.S. National Institutes of Health (NIH), outlined in the *Code of Federal Regulations* title 46.
- To certify that protection for human subjects meet appropriate standards, verifiable assurances of IRB approval must be submitted to the Association before final approval of Grant funding.
- 3) Grantee must adhere to the International Conference on Harmonization (ICH) for Good Clinical Practice (GCP). In addition, all relevant host country standards must be met.

The Principal Investigator and Grantee Institution have the ultimate responsibility for the conduct of research, including safeguarding the rights and welfare of human subjects throughout the course of the experiments.

C. Scientific Misconduct

The Association expects investigators and institutions to follow the National Institutes of Health (NIH) guidelines on research conduct in "proposing, performing, or reviewing research, or in reporting research results" (U.S. Code of Federal Regulations, title 42, §93.103). Grantee Institution is expected to have established procedures in place for addressing research misconduct and is charged with fostering research integrity through enforcement of its Institutional policies.

The Association's Panel on Ethical Scientific Programs (ESP) works on behalf of Association scientific programs and publications to objectively and efficiently investigate cases of potential or perceived misconduct. Grant data and research records, including the original versions of manuscripts, figures and other files and supporting materials, must be retained for a period of seven (7) years and must be produced for review by ESP, if requested. Refer to the Association's Policies and Procedures Related to Scientific Ethics and Integrity in Research Grants ("Misconduct Policy") for further details.

D. Audit Rights

Grantee and Grantee Institution shall keep copies of all relevant books and records and all reports to the Association for at least five (5) years after expiration or termination of the Grant. The Association may also verify any information contained in Grantee and Grantee Institution's reports by interviewing Grantee, Grantee Institution personnel and other persons. The Association may, at its own expense, monitor or evaluate the use of Grant Funds through various methods, including but not limited to site visits, third party evaluations and examination of books and records. Grantee and Grantee Institution shall help facilitate all such Association monitoring and evaluation efforts. This provision shall survive expiration or termination of the Grant.

E. U.S. Economic Sanctions, Anti-Terrorism and Anti-Money Laundering Laws

Grantee must comply with applicable United States economic sanctions, anti-terrorism laws, and anti-money laundering laws, including but not limited to the USA PATRIOT Act, the laws administered by the Office of Foreign Assets Control (OFAC) of the U.S. Department of the Treasury, Executive Order 13224 and any local laws that apply in the jurisdiction in which the Grantee is operating. Grantee certifies that Grantee takes reasonable steps to ensure that Grant Funds are not ultimately distributed to any person or entity designated as a Specially Designated National by OFAC (a list of which is online at treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx) and that Grantee takes reasonable steps to ensure that it does not support terrorist activity and/or terrorism-related training or money laundering. This provision must be included in all relevant subcontracts when applicable.

If Grantee Institution has U.S. tax-exempt status: Grantee Institution hereby each confirms, represents and warrants it is exempt from United States federal income tax and is an organization described in section 501(c)(3) under the Internal Revenue Code of 1986 (the "Code") and that it is not currently under audit by the Internal Revenue Service. Grantee Institution shall advise the Association immediately if there is any change to its exempt status during the term of the Grant.

VII. Relationship to Association

A. Independent Contractors

The Association, Grantee and Grantee Institution understand and agree that they each are at all times acting as independent contractors. Nothing in this Grant will be construed or deemed to create a relationship of employer and employee, partner, joint-venturer or principal and agent between Association and Grantee Institution, its faculty, employees, agents or officers. Except as expressly set forth in the Grant, Association shall neither have nor exercise any control or direction over the methods by which Grantee or Grantee Institution conducts the research and other work under the Grant.

B. Worker's Compensation

Grantee Institution faculty, employees, fellows, trainees and students participating in the Research Project will in no sense be considered employees of the Association and to the extent they are employees of Grantee Institution will remain as employees of Grantee Institution. The Association does not and will not assume any liability under any law relating to worker's compensation by reason of any Grantee Institution representative participating in the Research Project, receiving training or traveling pursuant to the Grant. Nothing in the Grant will be construed as a waiver by Grantee Institution of any rights it may have under any applicable law governing injury to workers. This provision shall survive expiration or termination of the Grant

C. Nonexclusive Relationship

The Association, Grantee and Grantee Institution understand and agree that nothing herein shall be interpreted as establishing any form of exclusive relationship between Grantee and the Association or between Grantee Institution and the Association. They further understand and agree that nothing herein shall be interpreted as precluding any party from entering into agreements similar to the Grant with third parties or from conducting educational, research or other activities that may involve the same or similar subject matter as the research support by the Grant Funds, the conduct of which is outside and independent of the Grant, providing that any such educational, research or other activities are not done in a manner that is inconsistent with the rights and obligations of the parties to the Grant.

D. Indemnified Parties

To the extent permitted by applicable law, Grantee and Grantee Institution (each an "Indemnifying Party") will defend, indemnify and hold harmless the Association, including its regents, directors, officers, employees and agents (collectively, the "Indemnified Parties"), from and against any and all losses, claims, liabilities, damages and costs of whatever kind and nature, including reasonable attorney fees and legal costs, for death or injury of any person and for loss or damage to any property, occurring or claimed to occur as a result of the negligence or willful misconduct of the Indemnifying Party, including its regents, directors, officers, employees, faculty, students and agents, or the failure of the Indemnifying Party to perform its obligations under the Grant; providing, however, the Indemnifying Party shall not be obligated to defend, indemnify and hold harmless any Indemnified Party to the extent any such losses, claims, liabilities, damages, and costs are the result of the negligence or willful misconduct of an Indemnified Party or the failure of an Indemnified Party to perform any obligation under the Grant. This provision shall survive expiration or termination of the Grant.

E. General Liability Insurance

Grantee Institution hereby notifies the Association that Grantee Institution maintains comprehensive general liability insurance coverage with limits of not less than \$1 million per occurrence and \$3 million annual aggregate (or an equivalent program of self-insurance satisfactory to the Association). Upon the Association's request, Grantee Institution will provide proof of insurance or loss coverage, required under the terms of the Grant. In addition, the Association agrees to notify Grantee Institution in writing in the event of a material modification or change in such coverage.