



# Pathway to Stop Diabetes Grant Stipulations

## **General Stipulations**

- Grantee is required to devote at least 75% of his/her time and effort to research during the Grant
  Period (includes research related and unrelated to the Project as defined in the Award Letter). The
  Grant Period is set forth in the Award Letter.
- All Grant Funds set forth in the Award Letter shall be used solely for the Project.
- Grantee is required to be a current professional member of the American Diabetes ("Association")
   Association ("Association") during the Grant Period. Information on Professional Membership may be found at <a href="http://professional.diabetes.org">http://professional.diabetes.org</a>.
- All requests and communications regarding the administration of the Grant (e.g. transfers, extensions, carry-over funds, IP reporting, etc.) and all reports required by the Grant must be made in writing to Pathway administration staff at <a href="mailto:pathway@diabetes.org">pathway@diabetes.org</a> and must include appropriate supporting documentation and utilize templates and forms that are provided at <a href="http://professional.diabetes.org/grants-pathway">http://professional.diabetes.org/grants-pathway</a>.
- The American Diabetes Association ("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 in other publicly accessible databases of privately funded grant awards. The Association also 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 and Grantee Institution shall avoid disclosing confidential information in lay abstracts and summaries provided to the Association, and mark any confidential materials as such prior to submitting to the Association. This provision shall survive expiration or termination of the Grant.
- 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 <a href="http://professional.diabetes.org/grants-pathway">http://professional.diabetes.org/grants-pathway</a> ("Pathway Grant Policies"), 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 the notice of termination shall be deemed waived and 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 (December 31<sup>st</sup>), 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 such termination shall be deemed waived and Association shall not be obligated to provide any reimbursement for such expenses, fees and costs. This provision shall survive termination of the Grant.

- The Grant may not be 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.
- Grantee may relinquish, i.e., terminate, the Grant for any reason upon prior written notice to Association.

### **Intellectual Property Rights**

• In consideration of the Grant, the Grantee Institution and Grantee both agree to the terms of the Association's Intellectual Property Policy ("IP Policy") and shall grant to qualified sponsor(s) of the Pathway Program, which sponsors are identified in the Award Letter, a first option to negotiate to acquire a royalty-bearing license to practice the Invention (as defined in IP Policy) and to make, have made, use and sell products using or incorporating the Invention. Grantee Institution and Grantee having an ownership interest in and to an Invention and qualified sponsor(s) will negotiate in good faith to determine the terms of a license agreement. This provision shall survive expiration or termination of the Grant. Qualified sponsors for each Grant are defined in the Award Notification and Acceptance Letter.

#### **Record Maintenance and Audit**

• Grantee Institution shall maintain adequate books and records to track 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. Grantee Institution shall keep adequate books and records to substantiate all expenditures. 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. Grantee Institution and Grantee shall keep copies of all relevant books and records and all reports to the Association for at least five 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's personnel and other persons. The Association may, at its own expense, monitor or evaluate the use of the 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.

#### **Budget Stipulations**

- Award Letters and renewal notifications ("Renewal Letters") are issued on an annual basis and are subject
  to Grantee's timely filing of Annual Progress Reports. Failure to timely file Annual Progress Reports, or to
  demonstrate adequate research progress as determined by Association staff, may result in reduction(s),
  nonrenewal, suspension or termination of the Grant, in the Association's sole discretion.
- Indirect costs are limited to 30% of the total direct costs. The total annual Grant Funds amount (direct + indirect costs) may not exceed \$325,000 per year.
- During the training phase of Initiator Awards (Phase I), indirect costs are limited to 10% of the total direct costs. The total annual Grant Funds amount (direct + indirect) for Phase I of Initiator Awards may not exceed \$100,000 per year.
- Grant Funds may not be used for rent for office or lab space, internet or telephone service support, custodial or administrative support, tuition, relocation costs, memberships or subscriptions.
- All Grant Funds will be made payable to the Grantee Institution, but are specifically granted to the named Principal Investigator and are transferable (with the Principal Investigator) between institutions.
- Salary allocations shall be in accordance with the Grantee's percent effort on the Project, and be within allowable salary guidelines stated for each Pathway Grant in the Application Instructions.
- Grantee shall not purchase equipment of greater than \$25,000 with Grant Funds without prior written
  approval by the Association. Unless otherwise agreed in writing, title to equipment will be vested in the
  institution at which the Grantee is conducting research. It is agreed that title to the equipment shall also
  be transferred to the new Grantee Institution if a Grant is transferred to another institution. Grantee and
  Grantee Institution agrees, 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.
- Once the Grant Notice and Acceptance Agreement has been executed by the Grantee and Grantee Institution and submitted to the Association, budget revisions greater than 25% in any budget category set forth in Grantee's approved Pathway Program application (including without limitation, Principal Investigator salary, Technical Personnel, Supplies, Equipment, Other) must be approved by the Association. Requests must be submitted in writing to Pathway administration and Grantee shall not implement changes in any budget category without prior written approval by the Association. Notwithstanding the foregoing, written approval is not required if the budget revision is less than 25% in each budget category, but a revised budget must be submitted to Pathway administration by email at pathway@diabetes.org.
- Under no circumstances will the Grant Funds be increased beyond the original amount set forth in the Award Letter.
- 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 institution (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 and the Grant, including its attachments. For further information regarding transfers, please see the Pathway grant website at <a href="http://professional.diabetes.org/grants-pathway">http://professional.diabetes.org/grants-pathway</a>.
- In the event of transfer, a Final Financial Report 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. The Final Financial Report template can be found on the Pathway grant website at <a href="http://professional.diabetes.org/grants-pathway">http://professional.diabetes.org/grants-pathway</a>. Any and all adjustments must be incorporated into the final reconciliation and accounting in the Final Financial Report. Any claims for reimbursement of any expenses, fees or costs incurred by Grantee or Transferor in accordance with the Grant prior to the Transfer Date submitted by Grantee or Transferor to the Association more than sixty (60) days after the Transfer Date shall be deemed waived by the Association 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 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.

- Unexpended Grant Funds may be carried over to the following year. To apply for a Grant Fund carry-over, the carry-over justification section of the applicable Annual Progress Report must be completed and submitted to the Association by the Annual Progress Report due date. Carry-over funding is determined on a case by case basis.
- 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 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 relinquished date stated in writing by the Grantee will be the honored end date. Within sixty (60) days after the relinquishment date, Grantee Institution shall return to the Association all Grant Funds (>\$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.
- A one (1) year no-cost extension may be considered upon written request to Pathway administration staff at <u>pathway@diabetes.org</u>. Requests must be received at least 2 months prior to the End Date stated in the Grant Award Letter.
- Grantees must submit to the Association a complete Cumulative Final Report, which includes a Final Scientific Report signed by the Grantee and a Final Financial Report signed by the Grantee and the Grantee Institution's fiscal office, 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 Report must cover the entire Grant Period defined in the original Award Letter, and any no-cost extension of the Grant Period. Any and all adjustments must be incorporated into the final reconciliation and accounting set forth in the Cumulative Final Report. This provision shall survive expiration or termination of the Grant.
- Within sixty (60) days after the earlier of (i) the Grant End Date or (ii) the termination of the Grant if the Grant it terminated prematurely, Grantee Institution shall return to the Association all Grant Funds (>\$25) not expended in accordance with the Grant. This provision shall survive expiration or termination of the Grant
- The Association reserves the right to reduce Grant budgets at its sole discretion.

## Acknowledgement

• 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. Grantee and Grantee Institution must acknowledge the

Association in all publications by including the language "Supported by the American Diabetes Association Pathway to Stop Diabetes Grant XX-XX-XXX" in the acknowledgement section of the publication.

- Copies of all publications resulting from Association supported research must be sent to Pathway administration staff at <a href="mailto:pathway@diabetes.org">pathway@diabetes.org</a>.
- 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.

#### **Reporting Requirements**

- Grantees must submit complete written Scientific Progress Reports and an Annual Financial Reconciliation
  Report (collectively, the "Annual Progress Reports") and a Cumulative Scientific and Financial Final Report
  ("Cumulative Final Report"). Forms for preparing the reports can be found at
  <a href="http://professional.diabetes.org/grants-pathway">http://professional.diabetes.org/grants-pathway</a>. The completed Annual Progress Reports and Cumulative
  Final Report must be signed by the Grantee and the Grantee Institution's fiscal office.
- Required Annual Progress Reports and Cumulative Final Report forms are considered transaction records/history for the Grant. By submitting a signed report, Grantee Institution and Grantee acknowledge the receipt and expense of Grant Funds for the reported grant term.
- Grantee must attend the annual Pathway Symposium each year of the Grant Period. As part of the Symposium, Grantee is expected to present the progress and results to date resulting from the Pathway Project. This presentation is considered to be part of the progress reporting requirement of the Grant.
- The Association reserves the right to reduce the Grant Funds amount by 5% for any year of the Grant in which a required Annual Progress Report is not received on or before the respective due date(s). At the Association's sole discretion, the 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.
- If the complete Cumulative Final Report is not received and determined to be complete by the Association by 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 payments of any or all of Grantee's existing Association grants (if applicable) until the Cumulative Final Report is received and deemed to be complete by the Association.
- Grantee and Grantee Institution shall respond to payment and/or administrative inquiries (such as requests for photos, Annual Progress or 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 6 months is grounds for Grant termination for non-compliance with the Grant terms.
- The Grantee agrees to participate in follow-up assessments of his/her scientific and professional progress. For a period of five 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 of grant mechanisms and the Pathway Program. This provision shall survive expiration or termination of the Grant.
- Grantee and Grantee Institution agree to use reasonable efforts to ensure that Grantee makes himself/herself available if requested by the Association to make presentations about his/her research to Association volunteers, staff, and potential donors. In response to a request from the Association, Grantee

shall also be available for a ceremonial presentation of the Grant either at the beginning of the Project or at subsequent years of funding.

## **Professional Standards & Legal Compliance**

- The Grantee and Grantee Institution agree that the Grantee Institution and all persons participating in the Project research support by the Grant Funds will conduct the research 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 Grantee institution policies including, but not limited to, animal use and welfare, human subjects, scientific and financial misconduct.
- For research Involving human subjects 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.
- For research involving vertebrate animals, the Grantee is responsible for providing humane care for
  vertebrate animals used in all research supported by the Grant Funds in whole or part, and obtaining
  approval from the Institutional Animal Care and Use Committee (IACUC), or equivalent institutional
  review body, prior to initiating research involving vertebrate animals and regularly thereafter according
  to institutional requirements. Grantee shall provide documentation of the review body approval to the
  Association upon its request.
- The 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 United States Treasury Department's Office of Foreign Assets Control, 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 the US Department of Treasury, Office of Foreign Assets Control (a list of which is to be found at http://www.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 or 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.
- If Grantee Institution Has Non-U.S. Organization Status: The Grantee Institution confirms, represents and warrants (a) it is a non-U.S. not-for-profit organization, (b) it has no presence in the United States, (c) to the best of its knowledge, it has no liability for any U.S. state or federal income taxes, and (d) that it is not currently under audit by the U.S. Internal Revenue Service. Grantee Institution also confirms, represents and warrants that it has been properly organized, operated, and recognized as a not-for-profit organization in the jurisdictions in which it operates, and that it is in good standing with the tax and other relevant authorities in those jurisdictions. Grantee Institution shall advise the Association immediately if (1) there is any change to its not-for-profit status or (2) it becomes the subject of any audit or investigation during the term of the Grant.

### **Relationship to Association**

- The Association, Grantee Institution and Grantee 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 this 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 this Grant.
- Grantee and Grantee Institution faculty, employees, fellows, trainees, and students participating in the research supported by Grant Funds in whole or part will in no sense be considered employees of Association and to the extent they are employees of Grantee or Grantee Institution will remain as employees of Grantee or Grantee Institution. Association does not and will not assume any liability under any law relating to worker's compensation by reason of any Grantee or Grantee Institution representative participating in the Project, receiving training, or traveling pursuant to this Grant. Nothing in this Grant will be construed as a waiver by Grantee or 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
- 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 this 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 this 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 this Grant.
- 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 this 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 this Grant. This provision shall survive expiration or termination of the Grant.
- Grantee Institution hereby notifies Association that Grantee Institution has and shall maintain during the
  Grant Period 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
  Association) during the Grant Period. Upon Association's request, Grantee Institution will provide
  Association proof of insurance or loss coverage, required under the terms of this Agreement. In addition,
  Association agrees to notify Grantee Institution in writing in the event of a material modification or change
  in such coverage.