American Diabetes Association

Pathway to Stop Diabetes

2023

Initiator Award

diabetes.org/grants pathway@diabetes.org

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

Table of Contents

ı.	GE	ENERAL APPLICATION INFORMATION	1
	Α.	PATHWAY PROGRAM PURPOSE AND SCOPE	.1
		Nominations	
		APPLICATIONS	
	_	DEADLINE	
	Ε.		
		NOTIFICATION	
		Status Changes	
	٥.	Contact Information Change	-
		Application Withdrawal	
	۸,	WARD GUIDELINES	
II.			
		PURPOSE	
		SUPPORT	
	C.	APPLICANT ELIGIBILITY STIPULATIONS	
		Open Data and Resource Sharing	
		Institutional Assurances	.5
		Sponsoring Institution Stipulations	-
	Ε.	Review Criteria	.7
	F.	BUDGET GUIDELINES	.7
		Salary for Principal Investigator	
		Technical Personnel	.7
		Subcontracts	.8
		Supplies	.8
		Equipment	.8
		Computer Equipment and Software	.8
		Other Expenses	.8
		Direct Costs	.8
		Indirect Costs	.9
		Budget Revisions	.9
III.	ΑF	PPLICATION INSTRUCTIONS	10
	Α.	NOMINATION	10
		Principal Investigator	
		Contact Information	
		ORCID Identifier	
		Association Membership	
		Work Permission	
	C	Award Administration	
	С.	Financial Office Contact Information	
		Payment Information	
		Grant Administration Office Contact Information	
	П	BUDGET	
		PROPOSAL DETAILS	
	۲.	Title of Proposal	
		Research Type	
		Diabetes Type of Proposed Research	
		Therapeutic Goal	
		Research Program Area	
		Scientific Abstract	1Z

	Mo	y Abstract	13
IV.	BODY	OF THE APPLICATION	14
	A. FILE	E FORMAT	14
	B. For	RMATTING REQUIREMENTS	14
	He	ader	15
	Foo	oter	15
	Tal	ble of Contentsble of Contents	15
		DY OF THE APPLICATION CONTENTS	
	1)	PI Biographical Sketch (5-page maximum)	17
	2)	Annotated Publications (1-page maximum)	17
	3)	Essay questions (1-page maximum)	17
	4)	Research Strategy (4-page maximum)	
	5)	References (Optional, 1-page maximum)	18
	6)	Open Data and Resource Sharing Plan (1-page maximum)	18
	7)	Budget Form and Budget Justification	18
	8)	Institutional Nomination Letter	
	9)	Collaborator(s) Biographical Sketch(es) (Optional)	
	10)) Letters of Recommendation	
	•) IRB/IACUC Approval	
.,	•	•	
٧.	APPLIC	CATION SUBMISSION	21

I. General Application Information

A. Pathway Program Purpose and Scope

The Pathway to Stop Diabetes Program intends to attract brilliant scientists at the peak of their creativity to diabetes research, and to accelerate their research progress by providing the necessary resources and support for conducting transformative science.

This call for nominations is prioritizing exceptional investigators that aim to advance existing knowledge and discovery gained from the basic sciences to its eventual translation into patient and population benefit. The ideal applicant will propose innovative translational research that will be an important step towards the eventual goal of improving the lives of people at risk of diabetes or living with the disease - and the *pathway* to this impact is clear.

Nominations are welcomed from all areas of diabetes translational research and span prevention, management and cure of all diabetes types (type 1, type 2 and gestational), diabetes-related disease states (obesity, prediabetes, and other insulin resistant states) and complications. The program intends to attract a broad range of expertise to the field of diabetes from various fields of science and technology, including medicine, biology, chemistry, engineering, mathematics, and physics.

Meet our 2022 Pathway Awardees:

Anna Kahkoska, MD, PhD, Gillings School of Public Health, University of North Carolina at Chapel Hill

Project: Fusing rapid-cycle testing and adaptive interventions: A scientific pipeline to translate and individualize evidence-based psychosocial and behavioral interventions in routine type 1 diabetes care.

This project seeks to investigate how to integrate and tailor evidence-based mental health resources and interventions into routine patient care for people living with type one diabetes. "Psychological well-being is foundational for reaching treatment goals in type 1 diabetes, and interventions that support behavioral and psychosocial aspects of living with diabetes are a critical aspect of providing comprehensive, person-centered care," said Dr. Kahkoska. "The Pathway award will allow me to build a scientific pipeline to translate interventions from research settings to the clinic and individualize them to meet each patient's unique needs."

Lisa Beutler, MD, PhD, Northwestern University Medical School

Project: Dissecting sugar-induced modulation of gut-brain circuits This project seeks to understand how sugar consumption alters the connection between the gut and the brain, and how this may link to obesity and type 2 diabetes.

"Excessive sugar intake is clearly linked with the development of diabetes and obesity, but the mechanisms underlying this association are not completely understood," said Dr. Beutler. "I want to determine how what we eat alters the activity of brain centers that control appetite and blood glucose at single-cell resolution. This will allow us to understand how certain diets promote the development of diabetes and obesity by disrupting neural activity. Ultimately, we hope this will lead to better treatments for obesity and its complications, including type 2 diabetes."

Updated March 2023 1 | Page

While most nominees are anticipated to focus on advancing existing discoveries into pre-clinical and early-stage clinical research ('bench-to-bedside'), ADA strongly encourages innovative later-stage translational research (bedside-to-community) where feasible. Applications focused on a single clinical trial are out of scope.

B. Nominations

Submissions will be accepted by institutional nomination only.

Each institution is allowed a maximum of **one** nomination per grant cycle. The nomination can be for one of the Pathway Program Award types: Initiator or Accelerator. Appropriate institutional representatives must complete a Nomination Form and provide an Institutional Nomination Letter.

The Pathway program seeks to bring new investigators and new perspectives to diabetes research. Supporting scientists with different backgrounds and experience is critical to achieving that objective. Pathway accepts nominations for exceptional investigators with medical and scientific backgrounds who propose innovative basic, clinical, translational, behavioral, epidemiological and health services research relevant to any type of diabetes, diabetes-related disease state or complication, **prioritizing translational research that will 'move the needle' to improve the lives of people with diabetes**. Pathway solicits nominations for candidates in all disciplines as applied to diabetes. In addition, nomination of scientists from diverse backgrounds, including minority groups that are underrepresented in biomedical research, is strongly encouraged. The challenges of comparing different research approaches and investigators across a broad spectrum are met by assembling a Mentor Advisory Group which consists of a diverse group of reviewers with content expertise that give careful consideration to all types of proposals during the review process.

C. Applications

The applicant, also referred to as the Principal Investigator (PI), must have the institution's nomination prior to submitting an application electronically. In addition, the application must be routed through and approved by the usual administrative channels of the Sponsoring Institution.

Applications must be submitted through the ADA's online grant management system, available through the Association's <u>website</u>. Emails and word processing files submitted outside the Grant Management Site will not be accepted.

D. <u>Deadline</u>

The submission deadline for Initiator applications is **August 1, 2023,** for a **December 31, 2023,** award start date. Electronic applications must be submitted by 5:00 PM Eastern Time on the deadline date.

E. Letters of Recommendation

Three Letters of Recommendation assessing the scientific abilities and potential of the applicant are required at the time of application.

Updated March 2023 2 | Page

The Grant Management Site requires blind submission of Letters of Recommendation. Each recommender must individually upload his/her Letter of Recommendation to the candidate's application in the Grant Management Site. All three letters must be uploaded to the application <u>prior to</u> submission. The system will prevent submission of any application without all three Letters of Recommendation uploaded by the application deadline.

It is the responsibility of the candidate to ensure that all three recommenders have submitted their letters on time. It is strongly suggested that all Letters of Recommendation be uploaded to the application a week before the deadline date. Due to potential institutional firewall issues, we propose asking your recommenders for a personal email address versus work email address.

F. Notification

The applicant will receive a confirmation email through the online application system to confirm successful submission of the application. Notification of the funding decision will be sent by early December to the PI email address as entered into the online application form. If the applicant does not receive a confirmation email within the indicated time frame, please contact pathway@diabetes.org.

There are two rounds of the review process: 1) Preliminary Review and 2) Final Review. Applicants will be notified of the disposition of their application only following the conclusion of the final review process. Applicants will be informed of the final decision regarding the funding of the application and whether the application was advanced to final review.

G. Status Changes

The PI must notify the Association in writing regarding any change in application status after submission. Status changes include the following:

Contact Information Change

Send an email to pathway@diabetes.org and specify the PI's name, application type, application title, and contact information changes.

Application Withdrawal

To withdraw a pending application, the applicant must complete and submit a Grant Application <u>Withdrawal</u> <u>Form</u> per the instructions on the form.

Updated March 2023 3 | Page

II. Award Guidelines

A. Purpose

The Pathway Initiator award is designed to support early career researchers who have distinguished themselves during their research training as exceptionally talented and promising research investigators with a high likelihood of establishing successful, independent research programs and making seminal contributions in diabetes research. These awards are highly competitive and intended to support particularly innovative and transformational ideas that have the potential to have an exceptional impact in diabetes with an emphasis on the investigator's potential to significantly transform diabetes through translational research ('moving the needle') to improve the lives of people with diabetes. These awards provide salary and research support for applicants during late stages of mentored training through establishment as independent research faculty.

B. Support

Awards will provide two distinct phases of research support. Combined support for Phase 1 and Phase 2 can total up to \$1,625,000 over up to seven years.

- <u>Phase 1</u> will support up to two years at up to \$100,000/year (including 10% indirect costs) for mentored research training to allow investigators to complete ongoing research, publish results, receive additional training and develop independent research plans. Phase 2 support will be approved by the Association contingent upon adequate progress in Phase 1, and receipt and approval of documentation verifying that:
 - 1. The candidate has obtained a faculty appointment at an accredited research institution
 - 2. The institution has agreed to provide adequate laboratory space necessary to perform the proposed research and adequate time (75%) to dedicate to research
 - 3. The institution provides the candidate with an adequate and protected start-up package
- <u>Phase 2</u> will support up to five years at up to \$325,000/year (including 30% indirect costs) for independent research.

C. Applicant Eligibility Stipulations

Candidates will be identified through institutional nominations. Applications will be accepted from only individuals with the appropriate institutional support; any applications received without the appropriate institutional nomination will be administratively disapproved.

Eligible applicants must currently be in research training positions (post-doctoral fellow, research fellowship) and can have no more than seven years of training since their doctoral degree.

Candidate's appointment at the Sponsoring Institution must be full-time. Rare exceptions to full-time positions may be granted on a case-by-case basis and must be pre-approved by Pathway administration staff prior to application submission.

Applicants must hold a MD, PhD, DMD, DO, PharmD, DVM or an equivalent health- or science-related degree.

Updated March 2023 4 | Page

Applicant fellowship positions must be at university-affiliated institutions or other non-profit research institutions within the United States and U.S. possessions.

Individuals must have permission to work within the U.S., either as U.S. citizens or permanent residents, or with appropriate work visas/permits. Institutional confirmation of permission to work within the U.S. will be required at the time of application submission.

Recipients of Initiator Awards cannot concurrently hold an NIH K99/R00 grant. All other Career Development awards are allowable (unless holding of concurrent awards is prohibited by the other granting agency).

One person must be specified as the PI; co-PIs are not permitted.

Initiator applicants must agree to devote at least 75% of total time and effort towards research during the period of Association funding with a commitment to the Initiator Award of 75-100% effort during Phase 1 and 50-75% effort during Phase 2 if funded. In other words, 75% of the PI's time overall must be dedicated to research. This percentage includes time dedicated to the Association-funded grant *in addition to* grants supported by other funding agencies.

Applicants are required to provide an Institutional Nomination Letter from the appropriate institutional representative responsible for the final approval of the nomination submission (Chair of Nominating Committee, Dean of Research, Division Head, etc.), co-signed by the applicant's Division or Department Head, delineating the institution's nomination and commitment to the applicant. In addition, applicants must provide a completed Nomination Form, signed by the appropriate institutional representatives, acknowledging the nomination and endorsing the grant application (see Sponsoring Institution Stipulations below). Nomination materials must be submitted through the Association's online Grant Management Site at the time of application. The Association will not accept such materials separately after the application deadline. *Applications submitted without the appropriate nomination forms are considered incomplete and will be administratively disapproved*.

Open Data and Resource Sharing

All data resulting from ADA-funded research that can be shared without compromising human subject protections must be shared to an approved open data repository within 6 months of publication or within 18 months of the conclusion of the funding period, if the study remains unpublished.

A listing of repositories recommended by NIH is available on our <u>website</u> within the Pathway application materials. Awardees are encouraged to use the repository most appropriate for the subject matter of the research conducted.

Resources developed with ADA grant funding are required to be made available to the broader scientific community. ADA-funded projects expected to generate unique model organism resources or genomic data must include specific plans for sharing and distributing. If sharing is not possible, the application must include an acceptable explanation and request for waiver.

In general, to the extent possible, ADA grantees are expected to share all scientific resources upon request for the advancement of research progress. While the data and resource sharing plan will not impact the application score, it is a requirement for submission.

Institutional Assurances

The Association requires IRB and IACUC assurances for human and animal subjects, respectively, if these are utilized in the funded research experiments/protocols. Funded applicants must obtain institutional IRB and/or IACUC approval and must submit documentation of this approval at one of the following times: 1) at the time of

Updated March 2023 5 | Page

application or by the start date of the award. The Association requires IRB and/or IACUC approval within 90 days of the award letter being sent. Award payments will be held until necessary approvals are received.

D. **Sponsoring Institution Stipulations**

Each institution is allowed a maximum of <u>one</u> nomination per grant cycle to one of the Pathway Program Award types: Initiator or Accelerator. Institutions <u>may not</u> submit nominations in multiple award types in a single grant cycle.

Nominations are accepted from U.S. accredited academic and non-profit research institutions. For the purpose of this award, an institution generally includes all associated departments, medical schools and graduate schools. Individual components of multi-component institutions (e.g., University of California Los Angeles and University of California Berkeley within the University of California system, or Harvard University and Beth Israel Deaconess Medical Center within the Harvard system) are sufficiently independent to be considered individual institutions. Institutions must have a unique (DUNS) and/or (IPF) number to be considered independent. If there is any uncertainty regarding institutional status regarding nomination, please contact pathway@diabetes.org for clarification.

Nomination of more than the one allowable nominee may result in the administrative disapproval of all nominations from the same institution.

The Association encourages nomination of individuals from diverse backgrounds, including minority groups that are underrepresented in biomedical research. For the purpose of this program, underrepresented racial and ethnic minority groups are defined as African American, Hispanic or Latino, American Indian or Alaskan Native, and Native Hawaiian or Other Pacific Islander descent.

The Association requires a signed Nomination Form from the institution certifying that the application has been routed through the usual administrative channels of the sponsoring institution, that the institution has reviewed and agreed to all <u>Policies and Stipulations</u> and has approved submission of the application.

An appropriate institutional representative responsible for the final approval of the nomination submission (Dean of Research, Nominating Committee Chair, Division Chair, etc.) must submit a letter of nomination on behalf of the institution, co-signed by the nominee's Division or Department Head, outlining the commitment of the institution to the nominee.

The letter of nomination from the sponsoring institution must:

- Provide rationale for institution's nomination of candidate, including why candidate is uniquely suited for the award.
- Certify that the candidate has the appropriate full-time position at the sponsoring institution as required by the award.
- Outline the candidate's responsibilities and ensure that at least 75% of the nominee's total time and
 effort will be allocated to research during the term of this award.
- Provide assurance of an academic commitment to the candidate and to the research proposal.
- Outline the institution's plans to support the long-term development of the candidate, including specific expectations for the individual's career course.

Updated March 2023 6 | Page

E. Review Criteria

Scientific excellence is the primary benchmark to be evaluated for all Pathway applications, with an emphasis on the investigator's potential to significantly transform diabetes through translational research ('moving the needle') to improve the lives of people with diabetes. The proposed research strategy serves as a reflection of the individual's capacity for innovation, creativity and collaboration. The review will include the following components:

Principal Investigator:

- Strong potential to establish independent diabetes research program
- Strong potential/proven ability for creativity, collaboration and innovation
- Institutional commitment

Research Strategy:

- Innovation and creativity
- Potential impact for understanding/treatment of diabetes
- Clarity of thought and approach

F. Budget Guidelines

The following budget stipulations apply to Initiator Awards:

Salary for Principal Investigator

Salary allocations should be in accordance with the PI's percent effort on the grant and be within allowable salary guidelines for each Pathway award phase.

- Phase 1 of the Initiator Award provides PI salary support for the required level of effort between 75-100% (full-time professional effort). Applicants may request up to a maximum of \$66,600 for PI salary support per year, plus 25% for fringe benefits.
- Phase 2 of the Initiator Award provides PI salary support for the required level of effort between 50-75% (full-time professional effort). Applicants may request up to a maximum of \$100,000 for PI salary support per year, plus 25% for fringe benefits.

The actual salary provided by the award is based on a full-time, 12-month appointment at the Pl's institution, the Pl's institutional salary, and the level of effort requested.

Technical Personnel

Technical personnel may receive salary and fringe benefits support in accordance with the percent effort on the grant, within allowable institutional salary guidelines. Technical personnel include any individuals working on the research project in a scientific or technical capacity. For example, collaborating investigators, postdoctoral fellows, lab technicians, nurses, statisticians and patient recruiters are all considered technical personnel. Administrative, secretarial and/or custodial personnel are **not** considered technical personnel and are ineligible to receive salary from this award. If technical personnel have not yet been hired or identified, simply note the position and indicate the individual is "TBD" (to be determined).

Updated March 2023 7 | Page

Subcontracts

Subcontracts should be indicated with the total amount included on the main budget form, with the itemized subcontract budget outlined on a subsequent budget form. Any indirect costs associated with a subcontract must be incorporated into the yearly maximum indirect costs allowed for the entire award (i.e., 10% of total direct costs in Phase 1 and 30% of total direct costs in Phase 2). The combined indirect costs for the grant and any subcontracts cannot exceed the maximum indirect rate allowed for the award.

Supplies

There is no limit on the amount of budget funds that can be used for supplies. A categorized supply list must be included on the required annual financial reports. Office supplies are not permitted to be categorized as a direct cost.

Equipment

Purchases of equipment greater than \$25,000 must be justified by the applicant and approved in advance by Pathway administration staff. The Association defines equipment as any item costing more than \$5,000 with a lifespan of two or more years.

Computer Equipment and Software

Computer equipment and software purchases are allowable. Any purchase greater than \$3,000 must be directly related to the research strategy and must be justified by the applicant and approved in advance by Pathway administration staff.

Other Expenses

Some examples of additional expenses eligible to be included in this category are as follows:

- Travel to diabetes-related scientific meetings
- Publication costs (page charges, reprint costs)
- Books
- Animal housing and acquisition costs

Direct Costs

Direct costs include any direct expenses toward performing and completing the research. The following items **cannot** be purchased with direct cost funds:

- Rent for office or lab space
- Telephone service or support, or internet service
- Non-technical (e.g., custodial or administrative) support
- Tuition
- Relocation costs
- Memberships and subscriptions (including American Diabetes Association Professional Section membership)
- Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) administration fees
- Grantsmanship consultant fees
- Visa or Legal fees
- Office supplies
- Liability insurance

Updated March 2023 8 | Page

This list is not exhaustive. Any questions about whether a particular item or service may be purchased with direct costs should be referred to the Association's Research Program Office. **The Association reserves the right to refuse to pay for items or services with direct costs**. Unsanctioned purchases will be deducted from the recipient's grant account.

Indirect Costs

For Initiator Awards, indirect costs are limited to an additional 10% of the direct costs during Phase 1 of the award, and 30% of the direct costs during Phase 2. For example, those applying for an Initiator Award are eligible to include indirect costs up to \$9,091 (10% of \$90,909) for a total of \$100,000 per year in Phase 1, and indirect costs up to \$75,000 (30% of \$250,000) for a total of \$325,000 per year in Phase 2.

Budget Revisions

Once an award is activated, revisions greater than 25% in any budget category (i.e., PI salary, Technical Personnel, Supplies, Equipment, Other) require written approval from Association staff. Under no circumstances will the total budget for a project be increased beyond the original terms.

Updated March 2023 9 | Page

III. Application Instructions

Applications must be submitted online via the official <u>Grant Management Site</u>. Emails and word processing files submitted outside the site will not be accepted.

Applicants must complete the online application form and upload the complete Body of the Application as an attachment in Portable Document Format (PDF). Applicants must convert the necessary components of the application into a single PDF document; multiple attachments and other formats will not be accepted. All award guidelines and stipulations for preparing applications must be followed (e.g., supporting documents, page limits, font sizes).

Follow the steps below to create a new application in the Grant Management Site. If you have any difficulties accessing the site, contact pathway@diabetes.org for assistance.

- 1. Access the website and navigate to Current Funding Opportunities Section
- 2. Click on the Pathway funding opportunities and expand the Initiator Award Category
- 3. Click the Create a New Application link at the bottom of the section.
- 4. Create a new user account, or log in using an existing account.
- 5. Complete the eligibility quiz to confirm your eligibility status be sure to respond candidly for accurate results. Submitted applications that do not meet the eligibility criteria will be administratively disapproved.
- 6. After successful completion of the quiz, the application process will begin.
- 7. After saving your work by clicking the "Save & Finish Later" button located within each section, you can log out and complete your application at a later time.
- 8. To resume an in-progress application, log in to your Grant Management Site account.

Required details for each section of the online form are outlined below.

A. Nomination

The applicant must attest to being the official nominee of the Sponsoring Institution and upload the signed Nomination Form.

B. Principal Investigator

Contact Information

The applicant must provide the institution's Tax ID and full name of the institution where the research will be conducted. **Incorrect or incomplete information may cause a delay in application and award notifications.** Do not abbreviate the institution's name. In addition to the institution's name, the current complete mailing address, phone number, fax number, and email address must be provided.

ORCID Identifier

<u>ORCID</u> (Open Researcher and Contributor ID) provides a unique, persistent identifier for researchers that supports automated linkages to the investigator's digital research output. PIs are required to have an ORCID identifier at the time of application. <u>Registration</u> is available free of charge.

Association Membership

All funded investigators will be required to be current professional members of the Association during the grant period. Professional membership is not required at the time of application. Information on professional membership may be found at http://professional.diabetes.org/membership.

Work Permission

All investigators must be able to legally work in the United States. Institutional confirmation of work permission will be required for all applicants.

C. Award Administration

Financial Office Contact Information

Please provide the name and contact information for your institution's financial officer. Please note that the PI must have the institution's approval prior to submitting an application electronically. **Incorrect or incomplete information may cause a delay in correspondence and payments.**

Payment Information

Applicants must provide the institution name and the current complete mailing address for award payments. Checks will be made payable to the institution as entered in the "Payee Institution Name" field. The institution name should be entered as it appears on the institution's W-9 Tax Certification Form. Incorrect or incomplete names may cause a delay in correspondence and payments.

Please note that the institution name to which checks should be made payable frequently differs from the institution name where the applicant is employed. For example, an applicant employed by the University of the American Diabetes Association may request that the check be made payable to the University of the American Diabetes Association, Research Foundation. Keep in mind there is a character count limit of 39 characters for this field. Please provide appropriate abbreviations if available (example: Association Research Foundation).

Grant Administration Office Contact Information

Applicants must provide the grant administration office email address and phone number. **Individual names and/or email addresses are not accepted.**

D. Budget

Enter the requested amounts for the total amount and each year of the award. A categorized budget form and budget justification must be included in the Body of the Application.

E. Proposal Details

Title of Proposal

Only the first letter of the title's first word should be capitalized. The title of the application should not have symbols, such as " β ." Instead of the symbol, type the full name. For example, instead of " β ," type "beta." The database system will convert all unfamiliar characters into illegible symbols.

Updated March 2023 11 | Page

Research Type

Indicate whether the proposed research basic, clinical, or translational. For the purpose of this award, clinical research is defined as research directly involving humans, and includes educational, psychosocial, behavioral, epidemiologic, and health services research as well as clinical studies of normal physiology and mechanisms of disease. Translational research is defined as research that accelerates the transition of scientific discoveries into clinical applications, by efficiently advancing knowledge of efficacy to the next level of clinical application.

Diabetes Type of Proposed Research

Select the diabetes category relevant to the proposed research:

- Both Type 1 and Type 2 Diabetes
- Type 1 Diabetes
- Type 2 Diabetes
- Gestational Diabetes
- Obesity
- Pre-diabetes/insulin resistance
- Monogenic

Therapeutic Goal

Select the therapeutic goal most relevant to the proposed research:

- Cure Diabetes
- Manage Diabetes
- Prevent Diabetes
- N/A

Research Program Area

Select up to three program areas that describe the type of research being proposed. Program areas may be used as a general guide to help match grant applications to appropriate reviewers; however, selecting any given area does not limit the proposal to a specific reviewer pool.

Scientific Abstract

(250-word maximum)

Proposal abstracts must be included only in the online portion of the application; abstracts must *not* be included as separate attachments or in the Body of the Application. The scientific abstract must not exceed 250 words. The scientific abstract must be a technical description of the proposed work that includes a background, hypothesis, supporting rationale, specific aims, research design, and relevance to a cure, prevention, and/or treatment of diabetes. The abstract should be written in the third person.

Abstracts should not include symbols, such as " α ." The Grant Management Site cannot support special characters, and any non-ASCII symbols will be converted to question marks ("?") upon submission. Use the full term instead of the symbol, e.g., used the term "alpha" instead of " α ".

Lay Abstract

(250-word maximum)

Proposal abstracts must be included only in the online portion of the application; abstracts must not be included

Updated March 2023 12 Page

as separate attachments or in the Body of the Application. The lay abstract must be a non-technical description of the proposed work, not to exceed 250 words. This description must not repeat the scientific abstract. Instead, use non-technical language so the general public that does not have a scientific background can understand. The non-technical description must include the study's purpose and significance to diabetes. Do not include confidential information in the lay abstract because if the award is funded, the lay abstract will become public information. The lay abstract must be written in the third person.

Abstracts should not include symbols, such as " β ." The Grant Management Site cannot support special characters, and any non-ASCII symbols will be converted to question marks ("?") upon submission. Use the full term instead of the symbol, e.g., use the term "beta" instead of " β ".

Move the Needle Explanation

(150-word maximum)

ADA's funding emphasis is on transforming the field of diabetes. We are prioritizing exceptional investigators that aim to advance existing knowledge and discovery gained from the basic sciences to its eventual translation into patient and population benefit. The ideal applicant will propose innovative translational research that will be an important step towards the eventual goal of improving the lives of people at risk of diabetes or living with the disease and, the pathway to this impact is clear. In no more the 150 words, applicants must describe how their proposed research has the potential to significantly improve the lives of people at risk of diabetes or living with the disease.

Animal and/or Human Experimentation

Indicate the type of IRB and/or IACUC approval that corresponds with the proposed research being conducted. The Association requires IRB and IACUC assurances for human and animal subjects, respectively, if these are used in the funded research. Funded applicants must obtain IRB and/or IACUC approval and must submit documentation of such approval.

If applicants already have an IACUC and/or approval for the project, it should be included in the Body of the Application.

IV. Body of the Application

A. File Format

Applicants must combine all requisite components of the application into **one (1) PDF document**, ordered and named in accordance with application instructions.

Hard copies, multiple attachments, or other formats will not be accepted and will result in administrative disapproval of application.

The Association advises that the applicants complete and acquire all required documents before creating the PDF. Hardcopy materials must be converted into electronic format before combining into the single PDF file. Applicants must scan hardcopy materials in order to create the required electronic file.

PDF-creation software is necessary to create a single merged PDF document. There are many options for PDF generator software, many of which are free or can be purchased at a nominal cost. Refer to www.grants.gov for a list of suggested PDF conversion programs. The Adobe Acrobat Reader free version will not create a PDF. Adobe Acrobat version 6.0 or later can merge electronic files into a PDF document by following these steps:

- 1. Click the Create PDF button from the toolbar.
- 2. Select From Multiple Files.
- 3. Browse for all of the required files that should go in your application.
- 4. Arrange the files in order by selecting the **Move Up** and **Move Down** options. Use the Table of Contents to determine page order.
- 5. Select **OK** after all the documents are in order.
- 6. The Body of the Application PDF document is created.
- 7. Save the combined file according to the following naming convention: Last Name, First Name Project Title. If Project Title is too long for the file name, use just the first five words.

The document header must include the applicant's name (Last Name, First Name) and type of application submitted (Initiator). The footer must contain the page number. The header and footer should be added to the PDF file *after* all sections have been merged and collated.

B. Formatting Requirements

Applications must abide by the following format specifications:

- Font: Use an Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.) Type density, including characters and spaces, must be no more than 15 characters per inch. Type may be no more than six lines per inch. Because font size can appear larger on a computer screen, applicants are responsible for printing the PDF and measuring the font size. Applications that do not adhere to these formatting requirements will not be reviewed.
- Font for Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes: Font may be a smaller point size, but it must be in a black font color, readily legible, and follow the font typeface requirement. Color can be used in figures; however, all text must be in a black font color, clear and legible.
- Margins: Margins must be at least one-half inch.

- Spacing: Single-spacing is acceptable.
- **Legibility:** The PDF document should be easy to read. The Association's Mentor Advisory Group members review many applications and respond favorably to organized, well-written proposals.

Header

Applicant name and award type must be in the header of the Body of the Application. Please format as last name, first name. For example: Smith, John.

Applicants can use Adobe Acrobat 6.0 or later to create the header across the entire combined PDF. Follow the steps below:

- 1. Select **Document**, followed by **Add Headers and Footers**.
- 2. Select the **Headers** tab.
- 3. Select right justification.
- 4. Type the applicant's last name and then the first name in the **Insert Custom Text** section.
- 5. Select Insert.
- 6. Select **OK** to see the header that was created.

Footer

Number the pages sequentially in the footer of the Body of the Application. The Table of Contents must be numbered as page 1 of the application, in order to correspond to the PDF file page. Applicants can use Adobe Acrobat 6.0 to create page numbers across the entire combined PDF. Follow the steps below:

- 1. Select **Document**, followed by **Add Headers and Footers**.
- 2. Select the Footers tab.
- 3. Select Insert in the Insert Page Number section.
- 4. Select Insert.
- 5. Select **OK** to see the page numbers that were created.

Table of Contents

The completed Body of the Application <u>must</u> include a Table of Contents, so reviewers can easily locate application contents. Each section of the Table of Contents must include the page number according to the final Body of the Application PDF file. If a section does not apply to the proposal, the applicant should enter "N/A" rather than leaving the page number blank. The Table of Contents must be numbered as page 1 of the application, in order to correspond to its position within the final Body of the Application PDF file.

The Table of Contents Template specific for the Initiator Award is available for download online., within the Initiator Application Materials section. An example of the Table of Contents is available on the following page. Applications that do not include a Table of Contents will be administratively disapproved.

Initiator Award Last name, First name

Project Title

Table of Contents (Sample)

		Page #
1.	PI Biographical Sketch (5-page maximum)	
2.	Annotated Publications (1-page maximum, 5 references)	
3.	Essay Question Responses (1-page maximum)	
4.	Research Strategy (4-page maximum)	
5.	References (Optional, 1-page maximum)	
6.	Open Data Sharing Resource Plan (1-page maximum)	
7.	Budget Form	
	a. Budget Justification (1-page maximum)	
8.	Nomination Letter from Institutional Representative	
9.	Collaborator(s) Biographical Sketch(es) (Optional)	
10	. Letters of Support (must be submitted independently)	
	a. Letter of Support from Graduate/Medical Training Advisor/ Mentor	
	b. Two Additional Letters of Support	
11	. IRB and/or IACUC Approval	
	(Only required if obtained by application submission deadline)	

C. Body of the Application Contents

Specifications for Body of the Application contents are described below. Begin each text section in the PDF file with the section label (e.g., Biographical Sketch, Annotated Publications, etc.).

Please note that the Association will not accept other materials that are not listed in the Table of Contents. Inclusion of any additional materials will result in administrative disapproval of application.

1) PI Biographical Sketch (5-page maximum)

The Association accepts the <u>NIH Biographical Sketch Format</u>. Applicants that do not have an NIH Biographical Sketch should use the automated NIH SciENcv utility to create one. The SciENcv tool is available through myNCBI at ncbi.nlm.nih.gov/sciencv.

2) Annotated Publications (1-page maximum)

Provide a list of your five most impactful publications to date and briefly describe the qualities of these publications that make them notable. Include examples that represent/demonstrate independence, innovative approaches and any other unique characteristics that demonstrate your qualifications for the award.

3) Essay questions (1-page maximum)

Provide answers to each of the following three essay questions, using specific examples.

- a) What makes your research strategy particularly innovative and important for people with diabetes? What makes it uniquely suited for this program rather than a traditional research grant program?
- b) Describe your most significant research accomplishments to date and the personal qualities/characteristics that were required for these accomplishments. For example, provide evidence of innovation and creativity, the ability to challenge paradigms, identify opportunities and take intellectual risks, establish collaborations, integrate diverse sources of information, or develop novel alternative approaches when new challenges or opportunities arose.
- c) What are your future career plans and how will this award further those objectives? What is your long-term commitment to diabetes research?

4) Research Strategy (4-page maximum)

The research strategy should provide a high-level description of your scientific question(s) and the strategy(ies) and approach(es) that you will employ to address this question. It should be written with a level of detail appropriate for reviewers who are knowledgeable of the field, but who may not be directly involved in the proposed area of research. The research strategy section is flexible in format and does not require a detailed project plan, description of methods or preliminary data. Figures are allowed but must be included in the 4-page limit.

The research strategy must address the following components:

- a) Scientific question(s)/specific problem(s) to be addressed
- b) Specific approach(es) that will be employed
- c) Significance and potential impact of the work
- d) The potential risks and challenges, and how they will be overcome

Updated March 2023 17 | Page

5) References (Optional, 1-page maximum)

References may be included but may not exceed 1 page. Applications exceeding any of these limits will be administratively disapproved.

6) Open Data and Resource Sharing Plan (1-page maximum)

The data and resource sharing plan must not exceed one page. It must address (1) a brief summary of data outputs and/or resources that the proposed research will generate; (2) anticipated date when data and resources will be shared (no later than 6 months post-publication or 18 months from the award end date); (3) proposed repository for data sharing (applicants should reference the list of ADA-approved repositories; if use of an unapproved repository is desired, the applicant will be required to request approval before funding commences); and (4) justification for why the data and resource sharing plan is strong.

Applicants should also address whether or not a data-sharing agreement will be required and, if so, provide a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not any conditions will be placed on their use). References to data and resource sharing may also be appropriate in other sections of the application.

A 1-page maximum request for waiver may be submitted in place of the Open Data and Resource Sharing plan, in *only* one of the following categories:

- Human Subject Protection (privacy regulations or consent of research participants)
- Superseding Regulations (laws or institutional policies)
- Intellectual Property (existing IP rights)

A waiver request form is available for download within the application materials. Upon application review, if a request for waiver is not approved and the grant is approved for funding, the PI will be required to submit a data and resource sharing plan. If a plan is not received, the grant will be declined for funding.

7) Budget Form and Budget Justification

A categorical budget must be included. The Excel spreadsheet budget template specific for the Initiator Award is available for download <u>online</u>, within the Pathway Initiator Application Materials section.

A one-page budget justification must include descriptions for expenses in each budget category, and justification for equipment purchase requests >\$25,000.

Please refer to the **Budget Guidelines** section for specific budget details.

8) Institutional Nomination Letter

The appropriate institutional representative (Chair of Nominating Committee, Dean of Research, Division Head, etc.) must delineate the institution's nomination and commitment to the applicant in an Institutional Nomination Letter. The letter must be included in the Body of the Application PDF file.

Letter should be addressed as "Dear American Diabetes Association Mentor Advisory Group." Letter must be signed by the institutional representative and co-signed by the Department or Division Head of the applicant, certifying that the department or division is aware of and agrees to the institutional commitment outlined in the letter.

Updated March 2023 18 | Page

The Letter must specifically address the following points:

- Provide rationale for institution's nomination of candidate, including why candidate is uniquely suited for this award.
- Certify that the candidate has the appropriate full-time position at the sponsoring institution as required by the award.
- Outline the candidate's responsibilities and ensure that at least 75% of their total time and effort will be allocated to research during the term of this award.
- Provide assurance of an academic commitment to the candidate and to his or her research proposal.
- Outline the institution's plans to support the long-term development of the candidate and specific expectations for the individual's career course.

9) Collaborator(s) Biographical Sketch(es) (Optional)

If applicable, the Association accepts biosketches from project collaborators. Collaborator biosketches should follow the NIH Biographical Sketch Format (5 page maximum). Applicants that do not have an NIH Biographical Sketch should use the automated NIH SciENcv utility to create one. The SciENcv tool is available through myNCBI.

10) Letters of Recommendation

Three Letters of Recommendation assessing the scientific abilities and potential of the applicant are required at the time of application. The Grant Management Site requires blind submission of Letters of Recommendation. Each recommender must individually upload his/her Letter of Recommendation to the candidate's application in the Grant Management Sit. All three letters must be uploaded to the application prior to submission. The system will prevent submission of any application without all three Letters of Recommendation uploaded by the recommenders by the application deadline. Due to potential institutional firewall issues, we propose asking your recommenders for a personal email address versus work email address.

It is the responsibility of the candidate to ensure that all three recommenders have submitted their letters on time. It is strongly suggested that all Letters of Recommendation be uploaded to the Grant Management Site a week before the deadline date. The Association will not accept letters separately after the application deadline.

Letters should be addressed as "Dear Mentor Advisory Group" and must be provided from each of the following individuals:

Current Mentor: The letter from the current mentor should specifically address the following points:

- The applicant's ability to advance to independence
- The applicant's ability to innovate and collaborate
- How the applicant compares to previous trainees (percentile ranking i.e. in the top 5% of previous trainees).

Graduate or Medical Training Advisor: If applicant cannot provide a reference from their direct graduate or medical training advisor, it must come from another individual specifically involved in the applicant's research or medical training at the graduate level. If the recommendation is not from the direct graduate or medical training advisor, the individual providing the reference must explain their

relationship with applicant (e.g. thesis committee member, or investigator other than advisor that was a close collaborator/co-author, or that the applicant worked closely with as a student). The letter should specifically address the following points:

- The applicant's potential to make significant contributions to diabetes research
- The applicant's ability to innovate and collaborate
- How the applicant compares to previous trainees (percentile ranking i.e. in the top 5% of previous trainees).

<u>Past or Current Collaborator</u>: The letters should specifically address the following points:

- The applicant's potential to make significant contributions in diabetes research
- The applicant's ability to innovate and collaborate

Letters must be uploaded to the online <u>Grant Management Site</u>. Individuals providing recommendations <u>must</u> submit the letter *directly* to the Association by uploading it to the grant application. *Please note that the Association does not accept letters separately after the application deadline date.*

11) IRB/IACUC Approval

Required for all applicants using human and/or animal subjects

A copy of the IRB/IACUC approval letter should be uploaded to the final PDF copy of the application if available. If approval is not obtained by the application deadline, a just-in-time submission by the funding start date of the award is acceptable.

Application submissions that are incomplete or do not adhere to section page limits will be administratively disapproved.

Updated March 2023 20 | Page

V. Application Submission

To complete the online application process at a later date, select **Save and Finish Later** at any point during the online application process. Saved applications can be accessed via the **Grant Management Site**.

Select **Review & Submit** when ready to submit an application. **Changes cannot be made to submitted applications.** The PI must have approval from the sponsoring institution prior to application submission. When application is submitted, the institution agrees to accept responsibility for the scientific and technical conduct of the research project and accepts all terms and conditions of the award.

Important Online Application Details

- 1. The online Grant Management Site utilizes cookies on your computer. To access the online application, you may need to:
 - a. Close all open browser windows
 - b. Clear your cache and cookies
 - c. Open a new browser window
 - d. Paste the link below into the address bar: https://www.GrantRequest.com/SID 320
 - e. Change your security setting to allow cookies
- Applications will not be saved unless applicant creates an account before beginning the process.
 Applications created without user accounts will have to start over with the online application process.
- 3. Changes cannot be made to submitted applications. Be sure to proofread your application carefully prior to submission.

Electronic applications must be submitted by **5:00 PM Eastern Time** on the deadline date. Any questions about online grant applications should be sent to pathway@diabetes.org.

Updated March 2023 21 | Page