



American Diabetes Association

Research Programs

July 2024

Innovative Research to Support the Psychological and Emotional Needs of People with Diabetes

Innovative Clinical or Translational Science Award

Application Instructions

professional.diabetes.org/grants

grantquestions@diabetes.org

National Office

2451 Crystal Drive, Suite 900
Arlington, VA 22202
professional.diabetes.org/grants

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

Table of Contents

I. BEHAVIORAL & MENTAL HEALTH INNOVATIVE CLINICAL OR TRANSLATIONAL SCIENCE AWARD 1	1
A. DEADLINE	2
B. INSTITUTIONAL APPROVAL	2
C. NOTIFICATION	2
D. STATUS CHANGES.....	2
<i>Contact Information Change</i>	2
<i>Application Withdrawal</i>	2
E. GRANT SUPPORT	2
F. REVIEW CRITERIA	3
G. ELIGIBILITY STIPULATIONS	3
<i>Faculty Appointment</i>	3
<i>Other Sources of Support</i>	3
<i>Open Data and Resource Sharing</i>	4
<i>Institutional Assurances</i>	4
<i>Confirmation of Study Drug</i>	4
H. BUDGET GUIDELINES.....	4
<i>Salary for Principal Investigator</i>	4
<i>Technical Personnel</i>	4
<i>Subcontracts</i>	5
<i>Supplies</i>	5
<i>Equipment</i>	5
<i>Other Expenses</i>	5
<i>Prohibited Expenses</i>	5
<i>Indirect Costs</i>	6
<i>Overlapping Funding</i>	6
II. ONLINE APPLICATION INSTRUCTIONS.....	7
A. PRINCIPAL INVESTIGATOR.....	7
<i>Contact Information</i>	7
<i>ORCID Identifier</i>	7
<i>American Diabetes Association Membership</i>	7
<i>Work Permission</i>	7
B. AWARD ADMINISTRATION.....	8
<i>Grantee Institution Information</i>	8
<i>Financial Office Contact Information</i>	8
<i>Payment Information</i>	8
<i>Grant Administration Office Contact Information</i>	8
C. PROPOSAL DETAILS	8
<i>Title of Proposal</i>	8
<i>Research Type</i>	8
<i>Diabetes Type of Proposed Research</i>	9
<i>Research Program Area</i>	9
<i>Scientific Abstract</i>	9
<i>Lay Abstract</i>	9
<i>Animal and/or Human Experimentation</i>	9
<i>Confirmation of Study Drug</i>	10
D. BUDGET.....	10
III. BODY OF THE APPLICATION.....	11
A. FILE FORMAT	11

B. BODY OF THE APPLICATION CONTENTS 11

 1) *Research Plan* 11

 2) *Open Data and Resource Sharing Plan (1-page maximum)* 12

 3) *References (5-page maximum)* 12

 4) *Manuscripts (Limit 2 manuscripts)* 12

 5) *Budget Form* 12

 6) *Budget Justification* 13

 7) *Facilities* 13

 8) *Biographical Sketch (5-page maximum per biosketch)* 14

 9) *All Sources of Support (for PI only)* 14

 10) *Letter(s) of Collaborative Arrangement* 14

 11) *Confirmation of Study Drug* 14

 12) *IRB/IACUC Approval(s)* 14

APPLICATION SUBMISSION 15

I. Behavioral & Mental Health Innovative Clinical or Translational Science Award

Background:

Diabetes is more than a physical health condition. The disease has significant behavioral, psychological, and social impacts. Diabetes self-management is demanding and complex. Activities such as monitoring blood glucose, utilizing insulin pumps or injecting insulin, taking oral medications, regular physical activity, and healthy eating all require a comprehensive understanding of diabetes. It also requires healthy coping mechanisms, and skills in problem-solving and risk reduction. This poses a burden and demands high levels of self-efficacy, resilience, and daily self-management. Emotional and mental health problems such as diabetes distress, depression, and eating disorders are common and associated with suboptimal glucose control, increased rates of complications, lower quality of life, and increased healthcare costs.

Depression is present in about one in four adults with diabetes. Individuals with Type 1 diabetes (T1D) and Type 2 diabetes (T2D) have nearly double the risk of suicide compared with the general population. Twenty-seven percent of teenagers with T1D report moderate to high risk of depression and 8% have suicidal thoughts. Diabetes distress is defined as the emotional response to the relentless burden of daily self-management, including the fear of complications, and social and financial challenges. Diabetes distress affects 33-50% of people with diabetes. Distress manifests as fatigue, tension, and burnout.

People with diabetes, especially young women, have high rates of disordered eating such as bulimia, binge eating, night eating syndrome, anorexia, and avoidant restrictive food intake disorder. Bulimia is the most common eating disorder in women with T1D whereas women with T2D are more likely to deal with binge eating.

American Diabetes Association's position statement "[Psychosocial Care for People with Diabetes: A Position Statement of the American Diabetes Association](#)" provides diabetes care providers with evidence-based guidelines for psychosocial assessment and care of people with diabetes and their families. Similarly, the ADA's "[Standards of Medical Care in Diabetes](#)" emphasizes the importance of integrating psychosocial screening and care with a collaborative, patient centered approach provided to all people with diabetes with the goals of optimizing health outcomes and health related quality of life. Despite the availability of evidence-based guidance only 25% to 50% of people with diabetes who have depression get diagnosed and treated. As such, there is an urgent need to more effectively address the psychological and emotional needs of people with diabetes so they may achieve optimal health and well-being.

Goal:

The mission of the American Diabetes Association is to prevent and cure diabetes and improve the lives of all people affected by diabetes. Mental health is an integral part of diabetes management, and the ADA seeks to close the wide gap between the psychological and emotional needs of people with diabetes and the care and support available. This request for applications (RFA) is soliciting proposals for interventional, generalizable, and scalable research to better understand and address how to improve all aspects of the integration of mental health care into clinical settings serving people with diabetes, especially for disadvantaged lower socioeconomic level families where health disparities are most evident.

Scope:

This call is focused on translational research to more effectively deliver personalized, patient-centered psychological and emotional care that considers the context of the person with diabetes, as well as their

individual values and preferences. Research areas may include but are not limited to strategies for improving patient communications and interactions, problem identification, psychosocial screening, diagnostic evaluation, intervention, and intervention scalability. For the purposes of this RFA, research proposals focusing on potential physiological and biological underpinnings of psychological conditions are out of scope.

A. Deadline

The submission deadline is **Thursday February 1st, 2024** with earliest award start date July 1, 2024. Electronic applications must be submitted online via the official Grant Management Site by 5:00 PM Eastern Time on the deadline date.

B. Institutional Approval

The applicant, also referred to as the Principal Investigator (PI), must have the institution's approval prior to submitting an application electronically. Although written confirmation is not required, PI must ensure that the Sponsoring Institution is aware of the grant application and has acknowledged its intent to fully support the award. In addition, PI must attest that the application has been routed through, and approved by, the usual administrative channels of the Sponsoring Institution.

C. Notification

The applicant will be sent a receipt of application confirmation email from Association Research Programs staff within four weeks of the application deadline. This notification will be sent to the applicant's email address as entered in the online application form. If the PI does not receive a confirmation email within the indicated time frame, please contact grantquestions@diabetes.org for assistance.

D. Status Changes

Applicants must notify the Association in writing regarding any status changes during the review period. Status changes include the following:

Contact Information Change

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

Application Withdrawal

To withdraw a pending application, the PI must complete the Grant Application Withdrawal Form and submit per the instructions on the form. The form is available by contacting research programs staff at grantquestions@diabetes.org.

E. Grant Support

The ADA Innovative Clinical or Translational Science Award provides up to \$200,000 per year for up to three years. The total award amount (direct plus indirect costs) cannot exceed \$600,000 for a three-year award, and the yearly total amount (direct plus indirect cost) cannot exceed \$200,000. Indirect costs cannot exceed 10% of requested direct costs.

Award funds must be used for research activities in the described project and are to be divided between the salary and project support. Support for the PI's yearly salary (including fringe benefits) cannot exceed 20% of total costs (direct plus indirect). Research support may be used to defray the costs of a

postdoctoral fellow, technician, supplies, equipment, travel, etc. Refer to the Budget Guidelines section of this document for specifics regarding allowable expenses.

F. Review Criteria

Applications will be evaluated on the potential of the research, if successful, to have a major impact on closing the wide gap between the psychological and emotional needs of people with diabetes and the care and support available. Alignment with the goals of the RFA, degree of innovation and scientific rigor are key considerations. Relevant experience of the Principal Investigator, availability of the appropriate facilities and resources, the ability of the investigator/site to recruit target populations, and/or show access to, and availability of, data sources, samples and study medications (if applicable) are also pertinent. The specific timeline for progress of enrollment, data analyses and/or other major project milestones and an appropriate budget allowing for the completion of the proposed work need to be stated.

Only LOIs invited to submit a full application will receive reviewer critiques, which will be sent within one (1) month of final notification. This applies to both funded and unfunded submissions.

Please note that this funding opportunity does not offer postdoctoral fellowships awards. Instead, ADA will be launching a separate open call for postdoctoral fellowship awards across all diabetes topic areas in Spring 2024.

G. Eligibility Stipulations

Applicant must hold a PhD, MD, PharmD, DO or DPM degree or, for other health professionals, the equivalent doctoral-level health- or science-related degree, and possess the necessary skills and training to carry out the proposed work.

Awards are limited to institutions within the United States and U.S. possessions. All investigators must be legally authorized to work in the U.S. Institutional confirmation of permission to work within the U.S. will be required for all applicants at the time of application submission.

One person must be specified as the Principal Investigator; multiple PIs/co-PIs are not permitted. Applicants cannot hold or apply for more than one Association Award at a time. Investigators currently funded through the Association's Program cannot apply for additional support, unless the existing award expires by the funding start date of the new award.

Faculty Appointment

At the time of application, Innovative Clinical or Translational Science Award applicants must hold a full-time independent faculty position or the equivalent at a university, university-affiliated research institution or other non-profit research institution. If an appointment is less than full-time, it must be noted on the budget page and fully explained on the budget justification page. Applications from PIs with less than a full-time appointment will be considered on a case-by-case basis.

Applicants from non-university research institutions must provide a letter from the proper institutional official to explain how the position of the applicant compares to a faculty position in a traditional academic institution. Any ambiguity about the applicant's position can negatively impact the application.

Other Sources of Support

Applicants must agree to devote sufficient time and effort to research to accomplish the aims of the proposal during the period of ADA funding.

Applicants must provide accurate and complete information regarding all other sources of research support (current and pending), including titles of grants, major goals/specific aims, funding amounts and periods, and role of the PI. **Ambiguity regarding other funding will result in administrative disapproval of the application.**

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 website under [Funded Research](#). 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 ADA requires IRB and IACUC assurances for human and animal subjects, respectively, if these are used in the funded research experiments/protocols. Applicants selected for funding must obtain confirmation of study drug approval and submit documentation of such approval within 90 days of the award letter being sent. Future award payments will be held until necessary approvals are received.

Confirmation of Study Drug

If the proposed research requires drug or drug placebo, and selected for funding, investigator must obtain IRB and/or IACUC approval and submit documentation of such approval within 90 days of the award letter being sent. Future award payments will be held until necessary approvals are received.

H. Budget Guidelines

Salary for Principal Investigator

PI salary support, including fringe benefits, cannot exceed 20% of total costs per year. Association staff assumes that appointments at the applicant's organization are full-time. If an appointment is less than full-time, it must be indicated with an asterisk (*) on the Budget page and fully explained on the Budget Justification page.

Technical Personnel

Technical personnel can receive salary from an ADA grant in accordance with the percent effort on the grant and 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 employees are **not** considered technical personnel and are ineligible to receive support from an ADA grant. If technical personnel have not yet been hired or identified, simply note that the person is "TBD" (to be determined).

As soon as additional personnel have been identified, PI must provide the ADA with the biographical sketch of individuals holding a graduate level degree or above.

Subcontracts

Individual subcontracts must be indicated on the main budget page and itemized subcontract budgets must be provided on a separate budget page. **Any indirect costs associated with a subcontract must be incorporated into the overall budget's yearly maximum indirect costs allowed (i.e., 10% of total direct costs) in the main budget.** The combined indirect costs for the grant and any subcontracts cannot exceed the 10% maximum indirect rate allowed for the award.

Supplies

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

Equipment

The Association defines equipment as any item costing more than \$5,000 with a lifespan of two or more years. PIs may not spend more than 20% of direct costs per year on equipment purchases. All equipment purchases must be itemized. Equipment not approved in the original proposal requires ADA written approval before being purchased. **Equipment purchases are not permitted in the final year of the award.**

Other Expenses

Other expenses must be itemized. Some examples of additional expenses eligible to be included in this category include:

- Travel to diabetes-related scientific meetings (limit of \$5,000 per year)
- Publication costs (page charges, reprint costs)
- Books (limit of \$500 per year)
- Animal housing and acquisition costs

Prohibited Expenses

The following items **cannot** be purchased with award funds:

- Rent for office or lab space
- Computer hardware or other smart devices (e.g., desktop, laptop, printer, iPad, smart phone)
- Telephone or internet service
- Non-technical (e.g., custodial or administrative) support
- Tuition
- Relocation costs
- Memberships and subscriptions (including ADA Professional Membership)
- IRB or IACUC administration fees
- Grantsmanship consultant fees
- Visa or legal fees
- Office supplies
- Liability insurance

This is not a complete list. Any questions about whether a particular item or service may be purchased with direct costs should be referred to the Association's Research Programs 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.

Indirect Costs

Indirect costs are limited to 10% of direct costs, and the yearly total amount (directs plus indirect costs) cannot exceed \$200,000 per year. For example, projects requesting \$200,000 per year are maximally allowed indirect costs of \$18,182 (at 10% of directs), with direct costs totaling \$181,818.

Overlapping Funding

If additional, overlapping support for the Association funded project is obtained from any other source at any time, funds awarded by the Association will be terminated, and any remaining uncommitted funds must be returned.

II. Online Application Instructions

Applications must be submitted online via the official Grant Management Site, available through the Association's website at professional.diabetes.org/grants. 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 grantquestions@diabetes.org for assistance.

1. Sign into your account at: https://www.GrantRequest.com/SID_320?SA=AM
2. Sign in with the same email and password used to complete the Letter of Inquiry
3. Once signed in, you will see the proposal form application link near the top left side
4. Click the link to begin your proposal

Required details for each section of the online form are outlined below. **Please note: some fields may be pre-populated from data in your original LOI submission. If changes are required, please include in your Body of the Application with a note explaining the reason for the change.**

A. Principal Investigator

Contact Information

The applicant must provide their full contact information, including institution email and office mailing address.

ORCID Identifier

ORCID (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. Registration is available free of charge online at orcid.org.

American Diabetes Association Membership

Award recipients are required to become members of and/or maintain membership in the Professional Section of the American Diabetes Association for the duration of their award. The membership fee cannot be paid with Association grant funds. If selected for funding, the PI must submit proof of Association membership prior to award activation. Membership is not required in order to submit a grant application.

Work Permission

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

B. Award Administration

Grantee Institution Information

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

Financial Office Contact Information

Applicants must provide the name and contact information for their institution's financial officer. All applicants must have the institution's approval prior to submitting an application electronically; however, a signature page is not required. **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.**

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: ADA 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 should be avoided.**

C. 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," use the term "beta." The Grant Management Site cannot support symbols, and any non-ASCII characters will be converted to question marks ("?") upon submission.

Research Type

Characterize the proposed research as basic, clinical or translational.

For the purposes of this award, basic research is defined as investigation into the fundamental cellular, molecular and biochemical mechanisms underlying the development, detection, treatment and management of diabetes and its complications.

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 (bench to bedside, clinic to community).

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

Research Program Area

Select up to three program areas that describe the type of research being proposed.

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 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”.

Animal and/or Human Experimentation

Indicate whether IRB and/or IACUC approval will be necessary for 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 experiment/protocol.

Applicants selected for funding must obtain IRB and/or IACUC approval and must submit documentation of such approval within 90 days of the award letter being sent. Future award payments will be held until necessary approvals are received.

If applicant already has IRB and/or IACUC approval, it must be included in the Body of the Application.

Confirmation of Study Drug

Indicate if the proposed research requires drug or drug placebo. The Association requires the investigator to demonstrate ability to obtain the needed research supplies. Applicants selected for funding must obtain confirmation of study drug approval and must submit documentation of such approval within 90 days of the award letter being sent. Future award payments will be held until necessary approvals are received. Acceptable forms of documentation can be 1) letter of agreement to provide drug from manufacturer or 2) allocation for drug supply cost within proposed budget.

If applicant already has documentation of drug supply, it must be included in the Body of the Application.

D. Budget

Enter the requested amounts for the total amount and each year of the award. An itemized budget form and budget justification must be included in the Body of the Application. A separate itemized Budget Form must be uploaded in Excel (.xls or .xlsx) for administrative purposes (included as an attachment in Invitation to Apply email).

III. Body of the Application

A. File Format

The required table of contents and research plan template was emailed to the applicant and must be used for submission (submitted as one single PDF file). *Hard copies, multiple attachments, or other formats will not be accepted and will result in administrative disapproval of application.*

B. Body of the Application Contents

Specifications for the Body of the Application contents are described below. Begin each text section in the PDF file with the section label (e.g., Resubmission Summary, Research Plan, Specific Aims, etc.).

The Association will not accept materials that are not listed in the Table of Contents Template. For example, an appendix with graphs/tables, additional data, more than 2 manuscripts, etc. will not be permitted and will be administratively removed from the application.

1) Research Plan

Complete a detailed plan of the proposed research following the outline below. Figures and tables must be included within the maximum page limits within each section of the Research Plan.

Applications that do not conform to these guidelines or exceed the maximum page limits within each section will be administratively disapproved.

The overall proposal should be kept as brief as possible while still presenting the complete research plan. As a panel of experts in the field will review proposals, established methods may be referred to by reference rather than described in detail in the proposal. New methodology or novel approaches should be described in detail. In general, the scope of the proposal should match the program budget. The following format must be used for the Research Plan:

a) Specific Aims (1-page maximum; 1-figure maximum)

Provide an overview of the proposed project, including a high level summary of the problem, relevance to the disease state and theoretical framework. Concisely state the goals of the work and summarize the expected outcome(s).

b) Significance and Innovation (1-page maximum)

(i) Significance

Explain the importance of the problem or barrier to progress in the field of diabetes research addressed by the project, and the necessity of the proposed work to the development of new knowledge in this research area. Describe how the expected results will make a clear and significant contribution to the field of scientific knowledge, technical capabilities and/or clinical practice for people with diabetes.

(ii) Innovation

Describe any novel theoretical concepts or approaches utilized or developed by the proposed work, and any new applications/improvements in methodologies, instrumentation or interventions.

c) Research Approach (8-page maximum)

Describe the overall strategy, methodology and analyses used to accomplish the specific aims of the project, integrating any preliminary data into discussion of the specific aim(s). Discuss any potential pitfalls and outline contingency plans. Particularly if the project is in the early stages of

development, address the management of any high-risk aspects of the proposed work and describe strategies to establish feasibility. Figures and tables must be included within the 8-page limit.

2) 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 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 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.

3) References (5-page maximum)

The references made in the Research Plan must not exceed five pages and must adhere to all formatting requirements. As applicable, the PI's name must be highlighted on all publications relevant to the application submission.

4) Manuscripts (Limit 2 manuscripts)

Applicants may include manuscripts that describe previous work related to the proposed research. Applicants cannot submit more than two manuscripts per application. Manuscript submissions do not have a page limit and are not required to be published at the time of submission.

5) Budget Form

An itemized budget using the Association's Budget Form must be included. Separate Budget Forms must be included for each individual subcontract. Refer to the Budget Guidelines section for specific details regarding allowable award costs. **The Budget Form was emailed to the applicant.**

6) Budget Justification

a) Professional Support (PI Salary and Technical Personnel)

List the name, position, organization, role, percent effort and capacity of each professional associated with the project according to the following format:

Jane Smith, PhD, Assistant Professor, Division of Endocrinology, State University
Principal Investigator (xx% effort/year)
 <Describe capacity here>

John Grant, PhD, Assistant Professor, Division of Physiology, University of State
Collaborating Investigator (xx% effort/year)
 <Describe capacity here>

Examples of professionals include the following:

- **Principal Investigator (PI):** The one applicant from the sponsoring institution who is responsible for the project's research design and technical direction. PIs must have a doctorate-level degree (e.g., MD, PhD, DPM, etc.). *The American Diabetes Association does not recognize co-PIs.*
- **Collaborating Investigator:** A person who devotes a considerable percent effort toward developing and/or implementing the research project. Collaborating investigators usually have doctorate or other professional degrees.
- **Consultant:** A person who has an independent role in developing or implementing the research project. Consultants tend to provide separate services that are performed within a certain amount of time or intermittently provide a certain technique and/or analysis for the project. Consultants usually have doctorate or other professional degrees.
- **Technical Personnel:** Any individuals working on the research project in a scientific or technical capacity. For example, postdoctoral fellows, graduate students, lab technicians, nurses, statisticians, and patient recruiters.
- **Other Professional:** A person who has qualifications in a specific area, such as biostatisticians, epidemiologists, etc.

b) Budget Categories

Provide a detailed budget justification corresponding to each budget category identified in the Budget Form (Supplies, Equipment, and Other Expenses). Categorize purchases by general item (glassware, chemicals, etc.) and include a dollar amount. Animal housing and acquisition costs may be included under "Other Expenses." Include the number of animals and price per animal (if purchased with award funds), and the facility's per diem animal care rate, if available. Provide further explanation/specific details if animal care costs are unusually large or small.

7) Facilities

Describe the facilities available to you for performing this research at your institution. The American Diabetes Association expects that PIs have designated lab space and office space specifically assigned to them.

8) Biographical Sketch (5-page maximum per biosketch)

Required for PI; any personnel included in the budget with a graduate degree or above; and any key professional regardless of whether they receive salary support from the project.

The Association accepts the [NIH Biographical Sketch Format](#). Applicants and/or technical personnel who do not have an NIH Biosketch should use the automated NIH SciENcv utility to create one. The SciENcv tool is available through myNCBI at ncbi.nlm.nih.gov/sciencv.

9) All Sources of Support (for PI only)

Complete the All Sources of Support Template, Sections (a-c), to provide details regarding the PI's completed, current and pending support. Ambiguity regarding other funding warrants administrative disapproval. If support for this project is obtained from other sources, the Association will withdraw any funds awarded. The All Sources of Support Worksheet is available for download within the application materials.

a) Funding Cap Eligibility Worksheet

The PI must complete the Funding Cap Eligibility Worksheet for current sources of support. The table should include **only** awards currently funded or with a known funding start date at the time of application submission. **Applications submitted without the requested information will be administratively disapproved.**

b) Completed, Current and Pending Funding

List the PI's completed, pending and current sources of support, including federal (NIH, VA, NSF, etc.), non-profit, industry, and other.

c) Previous American Diabetes Association Support

Indicate the PI's completed or active funding support from the American Diabetes Association.

10) Letter(s) of Collaborative Arrangement

Required from Collaborating Investigators, Consultants and/or Other Professionals

Collaborators must confirm their participation and amount of time devoted to the proposed research project. Letters of Collaboration are **not** intended to serve as Letters of Recommendation for the PI and should not read as such." A sample Letter of Collaboration is available for download within the application materials **The Association does not accept letters separately after the application deadline date.**

11) Confirmation of Study Drug

Required for all projects utilizing drug or drug placebo

If the proposed research requires drug or drug placebo, and selected for funding, investigator must obtain IRB and/or IACUC approval and submit documentation of such approval within 90 days of the award letter being sent. Future award payments will be held until necessary approvals are received.

12) IRB/IACUC Approval(s)

Required for all applicants using human and/or animal subjects

The ADA requires IRB and IACUC assurances for human and animal subjects, respectively, if these are used in the funded research experiments/protocols. Applicants selected for funding must obtain confirmation of study drug approval and submit documentation of such approval within 90 days of the award letter being sent. Future award payments will be held until necessary approvals are received.

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

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 through the Grant Management Site, available at professional.diabetes.org/grants.

Applicants must 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. Upon application submission, the Sponsoring Institution agrees to accept responsibility for the scientific and technical conduct of the research project and accepts all terms and conditions of the award.

Electronic applications must be submitted by **5:00 PM Eastern Time** on the deadline date. Any questions regarding the grant application process should be sent to grantquestions@diabetes.org.