



INNOVATIVE CLINICAL OR TRANSLATIONAL SCIENCE AWARDS

FULL PROPOSAL GUIDELINES

Innovative Clinical or Translational Science Awards: Full Proposal Instructions

Applications must be submitted online via SmartSimple, ADA's grant management system. Any application related files and other materials submitted outside the site will not be accepted.

For a detailed guide on how to log in to SmartSimple, create a new account, connect your user account to your Institution, and how to submit an application, see the **Pre-Award FAQ: Application Process in SmartSimple document**, available on the ADA website.

Applicants must complete the online application form and upload the complete *Body of the Application* as an attachment in pdf file format. 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 (i.e. supporting documents, page limits, font sizes).

Follow the steps below to open an application in SmartSimple. If you have any difficulties accessing the SmartSimple website, contact grantquestions@diabetes.org for assistance.

Follow the steps below to access your full proposal application in SmartSimple. If you have any difficulties accessing the site, contact grantquestions@diabetes.org for assistance.

1. Sign into your SmartSimple account with same email and password used to complete your Letter of Intent.
2. Once signed in, click on 'Research Portal' at the top of the page. Then, click on the folder icon labeled 'Applications'. You will see the full proposal application under the 'In Progress' tab. link near the top left side.
3. Click the '**Open**' button to access your full proposal application.
4. Save your work by clicking the '**Save Draft**' button located towards the bottom of each application tab. You can log out and complete your application at a later time.

Please note that some fields may be pre-populated with data from your original LOI submission. If updates are needed, please revise the scientific and lay abstracts accordingly, and include the updated information in the Body of the Application along with a brief explanation for the change.

PRINCIPAL INVESTIGATOR

Contact Information:

One person must be specified as the Principal Investigator. The applicant must share updated contact details from their user profile so that up-to-date information is reflected in the application. For a detailed guide on how to update contact details and important information related to the Principal Investigator, see *the Pre-Award FAQ: Application Process in SmartSimple* document, available on the ADA website. For administrative purposes, a current copy of the applicant's biosketch must be uploaded on their contact profile as a separate PDF file. The Association accepts the NIH Biographical Sketch Format.

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. Principal Investigators are required to have an ORCID identifier at the time of application. [Registration](#) is available free of charge. After updating your contact information in your SmartSimple account profile, select 'ORCID' from the side panel. The grant management system can import a user's ORCID account information, including funding and publication data, into their SmartSimple profile.

American Diabetes 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 <https://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.

AWARD ADMINISTRATION

Project Collaborators: Project Collaborators can be added to the application. Collaborators are affiliated with your institution, such as Key Personnel.

Research Officer: All applications must be submitted by a Research Officer from institution of the Principal Investigator. For detailed instructions on how to add key personnel to the application, review the *Pre-Award FAQ: Application Process in SmartSimple* document, available on the ADA website.

Financial Officer: All applications must have a Finance Officer from the institution of the Principal Investigator listed under the contacts section. The Finance Officer is designated by the Grantee Institution and is responsible for the proper accounting of grant funds. In this role, the individual is required to complete and certify the required annual Expenditure Reports.

FULL 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 "□." Instead of the symbol, type the full name. For example, instead of "□," type "beta." The grant system will convert all unfamiliar characters into illegible symbols.

Research Type: Indicate whether the proposed research is basic, clinical or translational.

- 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.

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.

Scientific Abstract (250 Word Maximum): 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. 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.

Abstracts should not include symbols, such as “α.” The grant management system 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): The lay abstract must be a non-technical description of the proposed work. This description must not repeat the scientific abstract. Instead, use non-technical language so the general public can understand without having a scientific background. The non-technical description must include the study’s purpose and significance to diabetes. If the award is funded, the lay abstract will become public information so please do not include confidential information. The lay abstract should be written in the third person. 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

Abstracts should not include symbols, such as “β.” The grant management system 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”.

RFA Alignment (250 Word Maximum): How does the proposed research directly aligns with the goal and scope of the RFA? How will the proposed research significantly impact outcomes for those individuals living with diabetes (move the needle)?

Animal and/or Human Experimentation

IRB/IACUC Approval is required for all applicants using human and/or animal subjects.

Indicate the type of IRB and/or IACUC approval that corresponds with the proposed research being conducted. If applicants already have an IACUC and/or approval for the project, it should be included in the body of the application and a copy of the IRB/IACUC approval letter should be uploaded to the final PDF copy, 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.

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

Confirmation of Study Drug: If the proposed research requires drug or drug placebo, the Principal Investigator must demonstrate having access to the necessary supplies by including the approval documentation in the Body of the Application and/or by the start date of the award. If funded, the Principal Investigator must obtain confirmation of study drug approval and must submit approval documentation within ninety (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.

Other Sources of Support: Principal Investigator must agree to devote sufficient time and effort to research to accomplish the aims of the proposal during the duration of the ADA award.

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 the ADA website. 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.

Budget Guidelines: Enter the total and annual requested amounts in the 'budget' tab of the application. You are required to enter a categorized budget with detailed line items and expense justifications.

Salary for Principal Investigator: Support for the Principal Investigator's salary, including fringe benefits, cannot exceed 20% of total costs per year. The salary should be proportional with the percent effort dedicated to this project, based on a full time 12-month appointment at their institution. 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 (*) within the budget template and provide a detailed justification.

Technical Personnel: Technical personnel may receive salary and fringe benefit 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). Applicants must provide a biographical sketch of all individuals with a graduate level degree or above who will receive a salary from this project as soon as they have been identified.

Subcontracts: During the full proposal stage, subcontracts should be indicated with the total amount included on the main budget, with the itemized subcontract budget outlined within the subsequent budget category. Please be aware that any indirect costs related to a subcontract must be included in the annual 10% indirect costs of the main budget. The total indirect costs for both the main budget and any subcontracts must not exceed the 10% maximum indirect rate permitted for the award.

Supplies: Supplies are general purpose consumable items that are used on a regular basis and have a shorter life span in use than equipment and machines. There is no limit on the amount of funding 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: The Association defines equipment as any item costing more than \$5,000 USD with a lifespan of two or more years. The Principal Investigator may not spend more than 20% of direct costs per year on equipment purchases. During the full proposal stage, all equipment purchases must be itemized in the budget template. Equipment not approved in the original proposal requires written approval from ADA Research Programs staff prior to being purchased. Equipment purchases are not permitted in the final year of the award.

Other Expenses: Other costs might include items that are not consumable but are needed on a regular basis, such as animal purchases and maintenance charges. During the full proposal stage, other costs must be itemized in the budget template.

A few examples of expenses eligible to be included in this category are as follows:

- Travel may include any domestic and/or international trips by key personnel related to the project and/or diabetes related conferences. Travel expenses are limited to \$5,000 USD per year unless otherwise approved by ADA Research Programs staff.
- Publication Costs (page charges, reprint costs)
- Books (\$500 USD limit)
- Animal Housing & Acquisition Costs

Direct Costs & Prohibited Expenses: Direct costs include any direct expenses toward performing and completing the research. The following items **cannot** be purchased with ADA grant funding:

- Rent
- Computer Hardware or Other Smart Devices (e.g., desktop, laptop, printer, iPad, smart phone)
- Office Telecommunications
- Internet Service
- Non-Technical Support (e.g., custodial or administrative)
- Tuition Reimbursement & Registration Fees
- 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
- General Office Supplies
- Liability Insurance
- Administrative Assistance Costs
- Equipment purchases are not permitted in the final year of an ADA award.
- Lobbying: American Diabetes Association grant funds may not be used for lobbying purposes of any kind.

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 Programs department. **The Association reserves the right to refuse to pay for items or services with direct costs.** Unsolicited purchases will be deducted from the recipient's grant account.

Indirect Costs: Indirect costs are limited to 10% of direct costs for each year of the award. The annual total amount for the project budget cannot exceed \$200,000 USD per year (direct costs plus indirect costs).

BODY OF THE APPLICATION

File Format

Applicants must combine all requisite components of the application into **one (1) PDF document**, ordered and named in accordance with application instructions. The required table of contents and research plan templates provide by ADA must be used for the submission.

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. 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.

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.

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 **must** 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, to correspond to its position within the final Body of the Application PDF file.

The Table of Contents Template specific for this grant mechanism is available for download online, within the RFA's *Application Materials* section on the ADA website. **Applications that do not include a Table of Contents will be administratively disapproved.**

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.).

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 these 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; as well as 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 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 RFA's *Application Materials* section on the ADA website. 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)

References may be included but may not exceed 5 pages. Applications exceeding any of these limits will be administratively disapproved. As applicable, the Principal Investigator's name must be highlighted on all referenced publications.

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

A categorical budget must be included. The Excel spreadsheet budget template specific for this award is available for download from the Research Programs section of the [ADA website](#), within the RFA's *Application Materials* section.

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

6) Budget Justification: The budget justification must include descriptions for expenses in each budget category

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, PI
Principal 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 the 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 available facilities at your institution that you will use to perform this research. The American Diabetes Association expects that Principal Investigators have designated lab space and office space specifically assigned to them.

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

A biographical sketch is required for the Principal Investigator and for 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 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.

9) Other Sources of Support (Principal Investigator only)

To adequately access an applicant's available percent effort, the Principal Investigator must provide accurate and complete information regarding all other sources of research support (both current and pending awards), including titles of grants, major goals/specific aims, funding amounts and periods, and project role. Ambiguity regarding other funding will result in administrative disapproval of the application. The applicant must complete the template found within the 'other support of support' section of the application. 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.

- **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 Principal Investigator and should not read as such. Letters of Collaborative Arrangement must be included in the Body of the Application PDF file. A sample 'Letter of Collaboration' is available for download under the RFA's *Application Materials* section on the ADA website. 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.

12) IRB/IACUC Approval(s)

Required for all applicants using human and/or animal subjects.

Application Submission

The Principal Investigator must submit the completed application to a Research Officer at their institution prior to full submission to the ADA. The Research Officer is responsible for completing the submission to the ADA in SmartSimple, ADA's grant management system. Any application related files or other materials submitted outside of SmartSimple will not be accepted. Changes cannot be made to submitted applications.

SmartSimple Link: https://diabetes.us-2.smartsimple.com/s_Login.jsp?lang=1&prole=0

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 grantquestions@diabetes.org.