

# American Diabetes Association

---

## Research Programs

---

July 2023

## Innovative Research to Improve the Lives of Women with Diabetes Across the Lifespan

Innovative Clinical or Translational Science Award

### Letter of Interest (LOI) Instructions

<https://professional.diabetes.org/research-grants>  
[grantquestions@diabetes.org](mailto:grantquestions@diabetes.org)

**National Office**  
2451 Crystal Drive, Suite 900  
Arlington, VA 22202  
[professional.diabetes.org/grants](https://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

<b>I. WOMEN’S HEALTH AND DIABETES INNOVATIVE CLINICAL OR TRANSLATIONAL SCIENCE AWARD .....</b>	<b>1</b>
A. DEADLINE.....	2
B. INSTITUTIONAL APPROVAL .....	2
C. NOTIFICATION .....	2
D. GRANT SUPPORT .....	2
E. REVIEW CRITERIA.....	2
<i>Eligibility Stipulations</i> .....	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
F. 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
<b>II. ONLINE INSTRUCTIONS .....</b>	<b>7</b>
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. REQUESTED BUDGET .....	8
C. PROJECT DETAILS.....	8
<i>Title of Proposal</i> .....	8
D. PROJECT SUMMARY .....	8
<i>Research Type</i> .....	8
<i>Diabetes Type of Proposed Research</i> .....	8
<i>Therapeutic Goal</i> .....	8
<i>Research Program Area</i> .....	8
<i>Scientific Abstract</i> .....	9
<i>Lay Abstract</i> .....	9
<i>RFA Alignment</i> .....	9
<b>III. RESEARCH PLAN .....</b>	<b>10</b>
A. FILE FORMAT .....	10
B. FORMATTING REQUIREMENTS .....	10
C. RESEARCH PLAN CONTENTS .....	10
1) <i>Research Plan (2-page maximum)</i> .....	10
<b>IV. LETTER OF INTEREST SUBMISSION .....</b>	<b>12</b>
<b>V. QUESTIONS? CONTACT US .....</b>	<b>12</b>

# I. Women's Health and Diabetes Innovative Clinical or Translational Science Award

The American Diabetes Association is requesting letters of Interest (LOIs) for research focused on innovative research to improve the lives of women with diabetes across the lifespan.

**Background:** Diabetes is one of the leading causes of cardiovascular disease (CVD), blindness, kidney failure and lower-limb amputation in women. Gender-specific differences affect screening, diagnostic and treatment strategies as well as the development of complications and mortality rates. Impaired glucose and lipid metabolism, body fat distribution and energy balance, and associated CVD are greatly influenced by steroidal and sex hormones. Compared with men, women have 25-50% greater excess risk for CVD with lower survival rates and poorer quality of life after heart attack. Women with diabetes have a 19% greater risk for the development of vascular dementia than men. Women with diabetes also have a higher risk for end stage kidney disease than men with the same condition suggesting that the female gender could accelerate disease progression. Furthermore, the pharmacokinetics and side-effects of drug therapies are different between the sexes.

The burden of diabetes is unique and can affect both mothers and their unborn children. In the United States, about 1-2% of pregnant women have pre-existing diabetes and about 6-9% develop gestational diabetes (GDM). Asian and Hispanic women have higher rates of GDM and black and Hispanic women have higher rates of pre-existing diabetes during pregnancy. Having diabetes during pregnancy increases the risk of babies being born large for gestational age (LGA) or developing obesity and type 2 diabetes (T2D) in the future. Higher HbA1c levels are associated with significantly increased risk of congenital malformations and stillbirth. Women with GDM have 5- to 7-fold increased risk of developing T2D within 5-10 years however only 30-70% of women receive screening after delivery.

As such, a better understanding of the sex and gender differences may improve care delivery and lead to better outcomes (more personalized care) for women with diabetes across the lifespan.

**Goal:** The mission of the American Diabetes Association is to prevent and cure diabetes and improve the lives of all people affected by diabetes. This request for applications (RFA) is soliciting proposals for research to better understand clinically important sex and gender differences to optimally inform prevention, diagnosis and treatment strategies for women across the lifespan and the development of sex-specific clinical guidelines where warranted.

**Scope:** While this call is broad in scope and encompasses basic through clinical research, significant emphasis will be placed on diabetes clinical research and translation. Examples of eligible applications may include, but are not necessarily limited to projects involving:

- Research to delineate clinically relevant sex-specific drivers of disparity in the risk for cardiovascular, kidney, cognitive complications (eg mechanistic studies using confirmed relevant models of human disease, translational studies leveraging predictive biomarkers, clinical data sets, patterns in access and adherence to guidelines directed therapies etc.)
- Research to improve screening and pregnancy outcomes in women with diabetes and reduce the risk of subsequent T2D In those with GDM
- Research to define genetic and psychosocial factors contributing to the unique aspects of diabetes in women across the lifespan.
- Research to improve understanding of disparities in process of care (for example CV and obesity management).

Importantly, submissions should indicate how the proposed research will have a significant impact on outcomes. For the purposes of this RFA, research proposals focusing on non-diabetic obesity and pre-diabetes are considered out of scope.

#### **A. Deadline**

The submission deadline for this LOI is **November 14, 2022** for anticipated July 1, 2023 funding. Electronic letters of interest (LOIs) 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 applying electronically. Although written confirmation is not required, PI must ensure that the Sponsoring Institution is aware of the grant and has acknowledged its intent to fully support the award. In addition, PI must attest that the grant has been routed through, and approved by, the usual administrative channels of the Sponsoring Institution.

#### **C. Notification**

Upon application submission, the applicant will be sent a confirmation of receipt for their Letter of Interest submission via email. **Applicants will receive updates on the status of their LOI no later than January 31, 2023.** This notification will be sent to the applicant's email address as entered into the online application form. If the PI does not receive a confirmation email within the indicated time frame, please contact [grantquestions@diabetes.org](mailto:grantquestions@diabetes.org).

#### **D. 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 for specifics regarding allowable expenses.

#### **E. Review Criteria**

Applications will be evaluated on the potential of the research, if successful, to have a major impact on the development, dissemination or implementation of effective interventions or strategies that improve outcomes for women with diabetes across the lifespan. 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. For fellowships, relevant experience and training history of the Mentor will be strong considerations. 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 Postdoctoral Fellowship (PDF) applications that are moved to full review will receive reviewer critiques, which will be sent within 1 month of final notification. This applies to both funded and unfunded submissions.

For all other award mechanisms (Junior Faculty Development, Innovative Basic Science, Innovative Clinical/Translational Science): Only LOIs invited to submit a full application will receive reviewer critiques, which will be sent within 1 month of final notification. This applies to both funded and unfunded submissions.

### 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 submission.

One person must be specified as the Principal Investigator; multiple PIs/co-PIs are not permitted.

Individuals may not currently hold another active ADA Award.

### Faculty Appointment

At the time of submission, ADA 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. Letters of interest (LOIs) 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 letter of interest (LOI).

### 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.

#### **Investigator Funding Cap**

***Due to fiscal constraints in research funding, the Association limits applicant eligibility to maximally support early career investigators and investigators at a higher level of need to maintain their existing research programs.***

Investigators with support as PI exceeding **\$500,000 in direct costs per submission year** are not eligible to apply. Non-profit/foundation, government, and investigator-initiated pharmaceutical/industry awards count toward the \$500,000 funding cap, but multi-center and industry-sponsored clinical trial grants are excluded from calculation.

Applicants cannot hold or apply for more than one Association Award at a time. Investigators currently funded through the Association's Research Programs cannot apply for additional support unless the existing award expires by the funding start date of the new 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 our website under [ADA-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 during the full application process for sharing and distributing. If sharing is not possible, funded applicants will be required to provide 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. Funded applicants must provide IRB and/or IACUC approval and submit documentation of approval(s) during the full application process or by the start date of the award. Award activation is contingent upon submission of proof of approval. If approval(s) are not received by the award start date, the award letter will not be provided.

### **Confirmation of Study Drug**

If the proposed research requires drug or drug placebo, the investigator must demonstrate having access to the needed research supplies by submitting documentation during the full application process or by the start date of the award. Award activation is contingent upon submission of proof of approval. If approval(s) are not received by the award start date, the award letter will not be provided.

## **F. Budget Guidelines**

### **Salary for Principal Investigator**

PI salary support, including fringe benefits, cannot exceed 20% of total costs per year. ADA 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 form 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

During the full application process, 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 submitted during the full application process. 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 during the full application process. 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 (\$500 limit)
- 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 Section 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 ADA’s Research Programs Office. **The ADA 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 Instructions

Letters of Interest and subsequent Invitation to Apply must be submitted online via the official Grant Management Site, available through the [ADA's website](#). Submissions outside the site will not be accepted.

Applicants must complete the online forms and upload the complete the applicable supporting documentation appropriate to the Letter of Interest (Research Plan) as a PDF attachment. Multiple attachments or other formats will not be accepted. All award guidelines and stipulations for preparing the Letter of Interest must be followed (e.g., supporting documents, page limits, font sizes).

Follow the steps below to create a new letter of interest in the Grant Management Site. If you have any difficulties accessing the site, contact [grantquestions@diabetes.org](mailto:grantquestions@diabetes.org) for assistance.

1. Click **Create a New Letter of Interest** at the bottom of the section
2. Create a new user account, or log in using an existing account
3. Complete the Eligibility Quiz to confirm your eligibility status – be sure to respond candidly for accurate results, submissions that do not meet eligibility criteria will be administratively disapproved
4. After successful completion of the quiz, the letter of interest process will begin
5. You may leave the site at any point by clicking **Save & Finish Later** at the bottom of the screen
6. After saving your work, you can log out and complete your submission at a later time
7. To resume an in-progress letter of interest, access [ADA's website](#) and select **Grant Management Site** on the navigation menu

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

### A. Principal Investigator

#### Contact Information

The applicant must provide the institution's full legal name where the research will be conducted. **Incorrect or incomplete information may cause a delay in letter of interest and award notification.** Do not abbreviate the institution's name.

#### 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 submission. [Registration](#) is available free of charge.

#### 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 ADA grant funds. If selected for funding, the PI must submit proof of ADA membership prior to award activation. Membership is not required at the time of letter of interest submission.

#### 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. Requested Budget**

Enter the requested total amount for the award.

## **C. Project Details**

### **Title of Proposal**

Only the first letter of the title's first word should be capitalized. The title of the proposal should not have symbols, such as "β." Instead of the symbol, type the full name. For example, instead of "β," type "beta." The Grant Management Site cannot support symbols, and any non-ASCII characters will be converted to question marks ("??") upon submission.

## **D. Project Summary**

### **Research Type**

Characterize the proposed research as clinical or translational.

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

### **Therapeutic Goal**

Indicate the ultimate therapeutic goal of the research being proposed:

- 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.

Abstracts should not include symbols, such as “ $\alpha$ .” 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 “ $\alpha$ ”.

**Lay Abstract**  
**(250-word maximum)**

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 “ $\beta$ .” 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 “ $\beta$ ”.

**RFA Alignment**  
**(250-word maximum)**

Applicants must detail how the proposed research directly aligns with the priorities and targeted focus area of the RFA and will have a significant impact on outcomes in those individuals living with diabetes.

### III. Research Plan

#### A. File Format

The required research plan template can be downloaded from the [ADA grants website](#).

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

#### B. Formatting Requirements

Submissions 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 at least 15 characters per inch. Since font size can appear larger on a computer screen, applicants are responsible for printing the PDF and measuring the font size. Submissions that do not adhere to these formatting requirements will not be reviewed.
- **Font for Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes:** Label fonts may be a smaller point size, but 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. Reviewers read many submissions and respond favorably to clear, organized, well-written proposals.

#### C. Research Plan Contents

Specifications for content are described below.

##### 1) **Research Plan (2-page maximum)**

Plan of the proposed research following the outline below. Figures and tables must be included within the two-page maximum limit. *LOIs 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**

Provide an overview of the proposed research, 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**

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.

**c) Research Approach**

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. Expected outcomes should also be provided. Figures and tables must be included within the page limit.

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

## IV. Letter of Interest Submission

To complete the online submission process at a later date, select **Save and Finish Later** at any point during the online submission process. Saved submissions can be accessed through the [Grant Management Site](#).

Applicants must select Review & Submit when ready to submit. Changes cannot be made to submissions. The PI must have approval from the sponsoring institution prior to submission and must agree to accept responsibility for the scientific and technical conduct of the research project and accepts all terms and conditions of the award.

### **Submission Issues? Troubleshooting Tips**

1. The Grant Management Site utilizes cookies on your computer. To access the online letter of interest, 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:  
[www.grantrequest.com/SID\\_320](http://www.grantrequest.com/SID_320)
  - e. Change your security setting to allow cookies
2. Submissions will not be saved unless applicant creates an account before beginning the process. Submissions created without user accounts will have to start over with the online process.
3. Changes cannot be made to submissions. Be sure to proofread your letter of interest carefully prior to submission.

Electronic submissions must be submitted by **5:00 PM Eastern Time** on the deadline date. Any questions regarding the grant process should be sent to [grantquestions@diabetes.org](mailto:grantquestions@diabetes.org).

## V. Questions? Contact Us

- Website URL: <https://professional.diabetes.org/research-grants>.
- For any questions, please contact [grantquestions@diabetes.org](mailto:grantquestions@diabetes.org).