INNOVATIVE CLINICAL OR TRANSLATIONAL SCIENCE AWARD

LETTER OF INTENT GUIDELINES

Innovative Clinical or Translational Science Awards: Letter of Intent Instructions

Applications must be submitted online via Blackbaud, ADA's grant management system. Proposal 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 Blackbaud. If you have any difficulties accessing the site, contact grantquestions@diabetes.org for assistance.

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

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

PRINCIPAL INVESTIGATOR

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

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

ORCID Identifier: 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.

American Diabetes Association Membership: All funded investigators will be required to be current professional members of the Association during the grant period. Please note that the membership fee cannot be paid with ADA grant funding. Professional membership is not required at the time of application. Additional information on ADA professional membership can 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.

PROJECT 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.

Requested Budget: Please enter the requested total amount for this project including indirect costs.

The following budget stipulations apply to Innovative Clinical or Translational Science Awards:

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.

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 form, with the itemized subcontract budget outlined on a subsequent budget form. 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 Program Office. **The Association reserves the right to refuse to pay for items or services with direct costs**. Unsanctioned purchases will be deducted from the recipient's grant account.

Indirect Costs: 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).

RESEARCH OVERVIEW

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 any 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’)?

LETTER OF INTENT: RESEARCH PLAN

Research Plan *(2 Page Maximum):*
The overall proposal should be kept as brief as possible while still presenting the complete research plan. As a panel of experts review your proposal, 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. 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 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 area of diabetes research addressed by the project, and the necessity of the proposed work to the development of new knowledge in this 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. 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 included. Figures and tables must be included within the page limit.

References *(1 Page Maximum):*
The references made in the Research Plan must not exceed one page and must adhere to all formatting requirements. As applicable, the Principal Investigator's name must be highlighted on all publications relevant to the LOI submission.

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 within the RFA's *Application Materials* section. 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: *IRB/IACUC Approval is required for all applicants using human and/or animal subjects.*

The Association requires IRB and IACUC assurances for human and animal subjects if they 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: 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 research supplies by submitting documentation during the full application stage and/or by the start date of the award. Award activation is contingent upon proof of approval. If approval(s) are not received by the award start date, the award letter will not be provided.

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

FILE FORMAT

Applicants must combine all requisite components of the application into one (1) PDF document, ordered and named in accordance with application instructions. ADA 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 to create the required electronic file.

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

Formatting Requirements: LOI's 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.
- **Spacing:** Single-spacing is acceptable.
- **Margins:** Margins must be at least one-half inch.
- **Legibility:** The PDF document should be easy to read. Reviewers read many submissions and respond favorably to organized, well-written proposals.

LETTER OF INTENT SUBMISSION

To complete the online application process at a later date, select **Save and Finish Later** at any point during the online application process. Saved applications can be accessed via Blackbaud, ADA's grant management system: https://www.grantrequest.com/SID_320/?SA=AM

Select **Review & Submit** when ready to submit an application. ***Changes cannot be made to submitted applications.*** The Principal Investigator must have approval from the Sponsoring Institution prior to application submission. When application is submitted, 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.

Important Online Application Details

1. Blackbaud utilizes cookies on your computer. To create a new online application, you may need to:
    a. Close all open browser windows
    b. Clear your cache and cookies
    c. Open a new browser window
    d. Open the RFA's page on the ADA website and paste the '**New Application'** link into the address bar.
    e. Change your security setting to allow cookies
2. Applications will not be saved unless applicant creates an account before beginning the process. Applications created without user accounts will have to start over with the online application process.
3. Changes cannot be made to submitted applications. Be sure to proofread your application carefully prior to submission.

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