American Diabetes Association

Core Research Program

2017

Innovative Clinical or Translational Science Award

professional.diabetes.org/grants
grantquestions@diabetes.org
# Table of Contents

## I. INNOVATIVE CLINICAL OR TRANSLATIONAL SCIENCE APPLICATION INSTRUCTIONS ................................................. 1

A. DEADLINE ................................................................................................................................................................................. 1
B. INSTITUTIONAL APPROVAL ..................................................................................................................................................... 1
C. NOTIFICATION ........................................................................................................................................................................... 2
D. APPLICATION ADDENDUM ...................................................................................................................................................... 2
E. STATUS CHANGES ..................................................................................................................................................................... 2
   - Contact Information Change ........................................................................................................................................... 2
   - Application Withdrawal .................................................................................................................................................. 2
F. GRANT SUPPORT ....................................................................................................................................................................... 2
G. REVIEW CRITERIA ................................................................................................................................................................. 3
H. ELIGIBILITY STIPULATIONS .................................................................................................................................................. 3
   - Faculty Appointment ....................................................................................................................................................... 3
   - Other Sources of Support ........................................................................................................................................... 3
   - Institutional Assurances ............................................................................................................................................... 4
   - Confirmation of Study Drug ....................................................................................................................................... 4
I. BUDGET GUIDELINES ............................................................................................................................................................ 4
   - Salary for Principal Investigator .................................................................................................................................. 4
   - Technical Personnel ......................................................................................................................................................... 4
   - Subcontracts ...................................................................................................................................................................... 5
   - Supplies .............................................................................................................................................................................. 5
   - Equipment .......................................................................................................................................................................... 5
   - Other Expenses .................................................................................................................................................................. 5
   - Indirect Expenses ............................................................................................................................................................. 6
   - Overlapping Funding ...................................................................................................................................................... 6
   - Budget Revisions ............................................................................................................................................................... 6

## II. ONLINE APPLICATION INSTRUCTIONS ...................................................................................................................... 7

A. PRINCIPAL INVESTIGATOR ...................................................................................................................................................... 7
   - Contact Information ......................................................................................................................................................... 7
   - ORCID Identifier ............................................................................................................................................................... 7
   - American Diabetes Association Membership ............................................................................................................... 7
   - Work Permission ............................................................................................................................................................. 8
B. AWARD ADMINISTRATION .................................................................................................................................................. 8
   - Financial Office Contact Information ............................................................................................................................ 8
   - Payment Information ....................................................................................................................................................... 8
   - Grant Administration Office Contact Information ...................................................................................................... 8
C. PROPOSAL DETAILS ............................................................................................................................................................... 8
   - Resubmissions .................................................................................................................................................................. 8
   - Title of Proposal ............................................................................................................................................................ 9
D. BUDGET .................................................................................................................................................................................... 9
E. PROJECT SUMMARY .............................................................................................................................................................. 9
   - Research Type ................................................................................................................................................................. 9
   - Diabetes Type of Proposed Research .................................................................................................................................. 9
   - Research Program Area .................................................................................................................................................. 9
   - Scientific Abstract .......................................................................................................................................................... 10
   - Lay Abstract ................................................................................................................................................................. 10
Animal and/or Human Experimentation ........................................................................................................... 10
Confirmation of Study Drug .............................................................................................................................. 10

III. BODY OF THE APPLICATION .......................................................................................................................... 11

A. FILE FORMAT ................................................................................................................................................... 11
B. FORMATTING REQUIREMENTS ........................................................................................................................... 11
   Header .............................................................................................................................................................. 12
   Footer ................................................................................................................................................................ 12
   Table of Contents .............................................................................................................................................. 12
C. BODY OF THE APPLICATION CONTENTS ...................................................................................................................... 14
   1) Resubmission Summary ........................................................................................................................... 14
   2) Research Plan (10 page maximum) ........................................................................................................... 14
   3) References (5 page maximum) ............................................................................................................... 15
   4) Manuscripts (Limit 2 manuscripts) ........................................................................................................ 15
   5) Budget Form ............................................................................................................................................ 15
   6) Budget Justification ................................................................................................................................. 15
   7) Facilities ................................................................................................................................................... 16
   8) Biographical Sketch (5 page maximum per biosketch) ......................................................................... 16
   9) All Sources of Support (for PI only) ........................................................................................................ 16
   10) Letter(s) of Collaborative Arrangement ............................................................................................... 17
   11) Confirmation of Study Drug .................................................................................................................... 17
   12) IRB/IACUC Approval(s) ........................................................................................................................... 17

IV. APPLICATION CHECKLIST ........................................................................................................................................ 18

V. APPLICATION SUBMISSION ........................................................................................................................................ 19

VI. QUESTIONS? CONTACT US ..................................................................................................................................... 19
I.  Innovative Clinical or Translational Science Application Instructions

Innovative Clinical or Translational Science Awards support creative and novel projects that hold significant promise for advancing the prevention, cure or treatment of diabetes. These awards are intended to support proposals that: 1) are high-risk but have potential for high-impact results, 2) extend existing knowledge into a new area or application, 3) utilize novel technological or cross-disciplinary approaches and/or 4) may not be sufficiently developed for traditional funding sources (e.g., NIH R01). Early and established investigators, including those who have not previously worked in the field of diabetes, may apply for this award.

To qualify for classification as a clinical or translational project, studies are expected to involve human subjects or human samples and/or data. For the purposes of this award, clinical science is defined as research where the effect of a change in the individual’s external or internal environment is evaluated, and includes therapeutic interventions, educational, psychosocial and behavioral research, health services/care delivery research and epidemiology. Epidemiological research is defined as research aimed at identifying the distribution and determinants of disease in a population.

Translational science 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. Translational research supported through this mechanism will typically involve expertise, collaboration and engagement across disciplines, and fall into one of two broad categories:

1) The first area includes efforts to translate basic biological discoveries from the laboratory into clinical applications that improve human health, including (but not limited to):
   - Laboratory to human studies clarifying the mechanisms of disease
   - Studies assessing the feasibility of applying laboratory discoveries to clinical investigations
   - Studies developing measures or markers of the presence, progression or improvement of diabetes or one or more of its complications

2) The second area is aimed at accelerating the movement of clinical advances from research settings to the community setting and enhancing the adoption of best practices in patient care, including (but not limited to) approaches such as:
   - Qualitative determination of the best methods to promote adoption of evidence-based practices
   - Retrospective or secondary analyses to generate future hypotheses
   - Health outcomes, comparative effectiveness or cost-effectiveness research

A. Deadline

The submission deadline is April 17, 2017 for anticipated January 1, 2018 funding. Electronic applications must be submitted online via the official Grant Management Site by 8:00 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. PI must confirm 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 applicant does not receive a confirmation email within the indicated time frame, please contact grantquestions@diabetes.org for assistance.

There are two rounds of the review process: 1) Preliminary Review and 2) Final Review. Status notifications will be distributed via email following each round of review. Written review comments will be provided for triaged applications following the completion of Preliminary Review. Applications that advance to Final Review will receive funding status notifications and written critiques at the conclusion of Final Review.

D. **Application Addendum**

An application addendum (optional) may be submitted following the close of the call for applications. Permitted addendum materials include only the following: 1) supporting manuscripts not available at the time of application (maximum combined total of two manuscripts per application), 2) proof of Institutional Animal Care and Use Committee (IACUC) and/or Institutional Review Board (IRB) approvals not available at the time of application, and 3) confirmation of study drug availability for clinical research (if applicable). **Preliminary data updates will not be accepted as an addendum.**

The deadline to submit an application addendum is **June 1, 2017**. The addendum must be submitted via the Grant Management Site using the online addendum submission form. Applicants will receive an automated email notification when the form is available through the site, approximately four weeks following the grant application deadline.

E. **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 for download on the Core Research Programs website within the Application Materials of the Innovative Clinical or Translational Science Award.

F. **Grant Support**

Innovative Clinical or Translational Science Awards provide 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 (page 4) for specifics regarding allowable expenses.

G. **Review Criteria**

The American Diabetes Association will give special emphasis to the following aspects in the evaluation of Innovative Clinical or Translational Science Award applications:

- The potential of the project to significantly impact the field of diabetes research and/or advance the prevention, cure or treatment of diabetes
- Whether the hypotheses to be tested are well-conceived, clearly stated and feasible; the degree of scientific rigor in study design
- The impact and innovation of the project, as assessed by the likelihood of the project to exert a significant and sustained influence on the involved research field(s) or extend existing knowledge into a new area or application, the utilization of novel technological or cross-disciplinary approaches, and/or the development of new lines of inquiry for further scientific investigation
- Potential clinical impact of the project, likelihood for advancement of clinical knowledge and the clinical utility of outcomes resultant from the study
- Relevant experience of the Principal Investigator/collaborator(s), availability of the appropriate facilities and resources, and an appropriate budget allowing for completion of the proposed work. The ability of the investigator/site to recruit the patient population; access to and availability of data sources, samples and study medications (if applicable); and the specific timeline for progress of enrollment, data analyses and/or other major project milestones

H. **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 certification of work permission will be required for all funded awards.

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

**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.
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 year are not eligible to apply for Association Core Program Awards. 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. For details, refer to the Funding Cap Eligibility Worksheet (All Sources of Support).

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 sources will result in administrative disapproval of the application.

Applicants cannot hold or apply for more than one Association Core Award at a time. Investigators currently funded through the Association’s Core Program cannot apply for additional Core support, unless the existing award expires by the funding start date of the new award.

Institutional Assurances

The Association requires IRB and IACUC assurances for human and animal subjects, respectively, if these are utilized in the funded research experiments/protocols. Funded applicants must obtain institutional IRB and/or IACUC approval and must submit documentation of this approval at one of the following times: 1) at the time of application, 2) by the addendum deadline, or 3) just-in-time (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, an award letter will not be offered and the grant will not be activated until all approvals have been received.

Confirmation of Study Drug

If the proposed research requires drug or drug placebo, the investigator must demonstrate the ability to obtain the needed research supplies by submitting documentation at one of the following times: 1) at the time of application or 2) just-in-time (submission by the start date of the award). If proof of drug supply availability is not received by the award start date, the award letter will not be offered and the grant will not be activated until all confirmation of ability to obtain study drug has been received.

I. 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 Association grant. 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 Association 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 Association 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 yearly maximum indirect costs allowed for the entire award (i.e., 10% of total direct costs).* 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 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 prior 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 device (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
- 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.

Budget Revisions
Once an award is activated, budget revisions greater than 25% in any budget category (PI salary, Technical Personnel, Supplies, Equipment, Other) require prior written approval from Association staff. Under no circumstances will the total budget for a project be increased beyond the original terms. The Association reserves the right to implement a penalty and/or hold the next payment until the issue is resolved for all budget revisions greater than 25% made without Association approval. Written approval is not required if the budget revision is less than 25% of the budget category; however, a revised copy of the budget must be submitted via email to grantadministration@diabetes.org.
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 (page 111) 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. Access the Core Research Programs website
2. Click on/expand the Innovative Clinical or Translational Science Award
3. Click Create a New Application 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 eligibility criteria will be administratively disapproved
6. After successful completion of the quiz, the application process will begin
7. You may leave the site at any point by clicking Save & Finish Later at the bottom of the screen
8. After saving your work, you can log out and complete your application at a later time
9. To resume an in-progress application, access professional.diabetes.org/grants 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 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, 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. 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.

Work Permission
All investigators must have permission to legally work in the United States. Institutional certification of work permission will be required for all funded awards.

B. Award Administration

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

Resubmissions
Applicants are permitted one resubmission of an application. There is no required time frame for resubmissions, but revised applications must follow the Application Instructions in effect at the time of resubmission. The revised application may be submitted to any subsequent application cycle, assuming all current eligibility requirements are met at the time of resubmission.

The title of the resubmission must be identical to the original application. All revised applications must begin with a Resubmission Summary, consisting of the original Notification Letter with complete review comments, followed by a summary response. The summary response must address substantive changes made to the application (2 page maximum, excluding the original review comments).

If the application is a resubmission, please enter the grant reference number assigned to the original application (example 1-17-ICTS-001), and indicate the application deadline date of the original submission.
**Only one revision of an unfunded application will be considered; the same application cannot be submitted a third time.** In order to be considered a new application, at least 50% of the content in the research plan must be changed, and the title must be different.

**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 “$\beta$.” Instead of the symbol, type the full name. For example, instead of “$\beta,”” type “beta.” The Grant Management Site cannot support symbols, and any non-ASCII characters will be converted to question marks (“?”) upon submission.

**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.

**E. Project Summary**

**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

Responses to this section will allow the Association to respond to external and internal inquiries regarding the funding percentage the Association provides for each type of diabetes.

**Research Program Area**

Select up to three program areas that describe the type of research being proposed. Topic areas are used primarily to categorize funding within the Association’s research portfolio and to assist in fielding external and internal inquiries regarding the various program areas we fund. While the program areas are used as a general guide to help match grant applications to appropriate reviewers, selecting any given area does not limit the proposal to a specific reviewer pool.
Scientific Abstract
(250 word limit)
Proposal abstracts should 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., use the term “alpha” instead of “α.”

Lay Abstract
(250 word limit)
Proposal abstracts should 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 simply repeat the scientific abstract. Instead, use non-technical language that is understandable to a layperson that does not have a scientific background. The non-technical description must include the study’s purpose and potential 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 prior to award activation.

If applicants already have IRB and/or IACUC approval for the project, it should be included in the Body of the Application. If the approval is pending, the Association will forward the approvals to the reviewers if received by the addendum deadline. The addendum deadline is June 1 for April applications.

Confirmation of Study Drug
Indicate if the proposed research requires drug or drug placebo. The Association requires the investigator to demonstrate the ability to obtain the needed research supplies. Applicants selected for funding must submit documentation of availability of drug supply prior to award activation. 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 should be included in the Body of the Application. If the approval is pending, the Association will forward the approvals to the reviewers if received by the addendum deadline. The addendum deadline is June 1 for April applications.

The Association will accept just-in-time submission of IRB and/or IACUC assurances and Confirmation of Drug Study. Applicants must submit approval by the funding date of January 1, 2018.
III.  Body of the Application

A.  **File Format**

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

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

The Association advises that applicants complete and acquire all required documents before creating the PDF. Hardcopy materials must be converted into electronic format (scanned) before combining into the single PDF 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 grants.gov for a list of suggested PDF conversion programs. The Adobe® Acrobat® Reader free version will **not** create a PDF. You can use Adobe Acrobat version 6.0 or later to 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 format) and the type of application submitted (e.g., Innovative Clinical or Translational) The footer must contain the page number. The Table of Contents must be numbered as page 1 of the application. The header and footer should be added to the PDF file **after** all sections have been merged and collated.

B.  **Formatting Requirements**

Applications must abide by the following format specifications:

- **Font**: Use an Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.) Type density, including characters and spaces, must be 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. Applications 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. Research Grant Review Committee members read many applications and respond favorably to clear, organized, well-written proposals.

**Header**

Applicant name and award type must be in the header of the Body of the Application, see page 12 for example. Applicant name should be in last name, first name format. For example: Smith, John.

Applicants can use Adobe Acrobat 6.0 or later to create the header across the entire combined PDF by following the steps below (instructions vary by software versions; refer to program’s ‘Help’ function for assistance):

1. Select **Document**, followed by **Add Headers and Footers**.
2. Select the **Headers** tab.
3. Select left justification.
4. Type the required information in the **Insert Custom Text** section. See page 12 for example.
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 or later to create the header across the entire combined PDF by following the steps below (instructions vary by software versions; refer to program’s ‘Help’ function for assistance):

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 document. If a section does not apply to the proposal, the applicant should enter “N/A” rather than leaving the page number blank. The Table of Contents must be numbered as page 1 of the application, in order to correspond to its position in the final combined Body of the Application PDF file. The Table of Contents Template is available for download on the Core Research Programs website within the Application Materials of the Innovative Clinical or Translational Science Award. A sample Table of Contents is available on the following page.
**EXAMPLE**

Innovative Clinical or Translational Science Award  

Last name, First name

*Project Title*

**Table of Contents**

<table>
<thead>
<tr>
<th>Page #</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Resubmission Summary .................................................................</td>
</tr>
<tr>
<td>a. Original Status Notification ..................................................</td>
</tr>
<tr>
<td>b. Summary Response (limit 2 pages) .............................................</td>
</tr>
<tr>
<td>2. Research Plan (limit 10 pages) ................................................</td>
</tr>
<tr>
<td>a. Specific Aims (1 page maximum; maximum 1 figure) .......................</td>
</tr>
<tr>
<td>b. Significance and Innovation (1 page maximum) ...........................</td>
</tr>
<tr>
<td>c. Research Approach (8 pages recommended) ...................................</td>
</tr>
<tr>
<td>3. References (limit 5 pages) ......................................................</td>
</tr>
<tr>
<td>4. Manuscripts (limit 2 manuscripts) ............................................</td>
</tr>
<tr>
<td>5. Budget Form ..................................................................................</td>
</tr>
<tr>
<td>6. Budget Justification .....................................................................</td>
</tr>
<tr>
<td>a. Professional Support .................................................................</td>
</tr>
<tr>
<td>b. Budget Categories .......................................................................</td>
</tr>
<tr>
<td>7. Facilities ......................................................................................</td>
</tr>
<tr>
<td>8. Biographical Sketch(es) (5 page maximum per biosketch) ...............</td>
</tr>
<tr>
<td>9. All Sources of Support <em>(for PI only)</em> ........................................</td>
</tr>
<tr>
<td>a. Funding Cap Eligibility Worksheet ..............................................</td>
</tr>
<tr>
<td>b. Current and Pending Support .....................................................</td>
</tr>
<tr>
<td>c. American Diabetes Association Support .......................................</td>
</tr>
<tr>
<td>10. Letters of Collaborative Arrangement ..........................................</td>
</tr>
<tr>
<td>11. Confirmation of Study Drug <em>(only if obtained by application deadline)</em></td>
</tr>
<tr>
<td>12. IRB and/or IACUC Approval <em>(only if obtained by application deadline)</em></td>
</tr>
</tbody>
</table>

*Updated December 2016*
C. **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) **Resubmission Summary**

   *Required for applicants submitting a revised application*

   The title of the resubmission must be identical to the original application. Revised applications are required to include a Resubmission Summary, consisting of the complete review comments from the original application, followed by a summary response to the criticisms and issues raised.

   Substantial scientific changes must be clearly indicated in the text of the application by bracketing, indenting, or change of typography. Do not underline or shade changes. Deleted sections should be described but not marked as deletions. If changes are so extensive that essentially all of the text would be marked, explain this in the summary response. Ambiguity about changes from the original application will severely hamper the review process.

   a) **Original Status Notification**

      The notification sent to applicants with review critiques of the original application must be included at the beginning of the Resubmission Summary portion of the Body of the Application.

   b) **Summary Response (2 page maximum)**

      Must not exceed two pages; original critiques from reviewers do not count towards the page limit of summary response to the criticisms and issues raised. Summarize substantial additions, deletions and changes made in response to reviewer comments.

2) **Research Plan (10 page maximum)**

   Complete a detailed plan of the proposed research following the outline below. The Research Plan must not exceed ten pages. Figures and tables must be included within the 10-page limit. Applications that do not conform to these guidelines or exceed the page limits 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 pages 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.

3) References (5 page maximum)
The references made in the Research Plan must not exceed five pages and must adhere to all formatting requirements stated on page 10. 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.

The Association will forward manuscript(s) not included at the time of application submission to the reviewers if received by the addendum deadline (June 1). All applications must still adhere to the limit of two manuscripts per application.

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 (page 4) for specific details regarding allowable award costs. The Budget Form is available for download on the Core Research Programs website within the Application Materials of the Innovative Clinical or Translational Science Award.

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>
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 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.
a) **Funding Cap Eligibility Worksheet**
   In addition, 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 (January 1- December 31). *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. *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 proposal requires drug or drug placebo, investigator must demonstrate the ability to obtain the needed research supplies. A letter confirming drug supply must be included in the Body of the Application, if available. If confirmation is not obtained by the application deadline, proof of drug supply must be submitted just-in-time by the start date of the award. An award letter will not be offered and the grant will not be activated until proof of drug supply is received.

12) **IRB/IACUC Approval(s)**
   *Required for all applicants using human and/or animal subjects*
   A copy of the IRB/IACUC approval letter should be included in the final PDF copy of the application, if available. If approval is not obtained by the application deadline, approval can be submitted by the addendum deadline (June 1) or just-in-time by the start date of the award (January 1). If approval is not received by the award start date, an award letter will not be sent and the grant will not be activated until approval is received.

   *Incomplete application submissions will be administratively disapproved.*
IV. Application Checklist

Prior to submission, all applicants should check their application for the following:

1. PI does not hold an existing ADA Core Program Award that does not expire by the start date of this award.

2. PI is legally authorized to work in the United States or U.S. possessions.

3. Proposal has been routed through and approved by the usual administrative channels of the sponsoring institution prior to application submission to ADA.

4. Required questions answered on the online form.

5. For revised applications, copy of complete critique and summary response included in the Body of the Application.

6. PI holds an MD, PhD, DMD, DO, PharmD, DVM, or the equivalent health- or science-related degree.

7. PI confirmed less than $500,000 of direct support on Funding Cap Eligibility Worksheet.

8. Appropriate budget form and justification are complete and included in the Body of the Application PDF.


10. Proof of drug supply included in Body of the Application if applicable; if not available, proof of drug availability to be submitted no later than the funding start date.

11. Proof of appropriate IRB and/or IACUC approval included in the Body of the Application; if required approval forms are not available, applicants must submit approval(s) either by addendum deadline or no later than the award start date.

12. Body of the Application is complete as described in the Application Instructions.

13. Body of the Application uploaded to the online application as an attachment.

Incomplete applications will be administratively disapproved.
V. Application Submission

To complete the online application process at a later date, select Save and Finish Later at any point during the online application process. Saved applications can be accessed 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 8:00 PM Eastern Time on the deadline date. Any questions regarding the grant application process should be sent to grantquestions@diabetes.org.

VI. Questions? Contact Us

- Website URL: http://professional.diabetes.org/grants
- For answers to Frequently Asked Questions, please access FAQ’s on our website.
- For grant application and eligibility questions, please contact grantquestions@diabetes.org.

Submissio n Issues? Troubleshooting Tips

1. The Grant Management Site utilizes cookies on your computer. To access the online application, you may need to:
   a. Close all open browser windows
   b. Clear your cache and cookies
   c. Open a new browser window
   d. Paste the link below into the address bar: www.grantrequest.com/SID_320
   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.