



*dedicated to finding a cure*

# **JDRF APPLICANT GUIDELINES INCLUDING GRANT MECHANISMS' DESCRIPTIONS & SCIENTIFIC GUIDELINES**

**Updated December 2008**

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# SECTION 1: APPLICANT GUIDELINES

## INTRODUCTION

[JDRF](#) is a global funding agency with a substantial proportion of its grants awarded outside the United States. We encourage any and all qualified researchers interested in addressing the scientific and clinical challenges and gaps to cure type 1 diabetes and its complications to apply for funding. Decisions on funding are based on the quality, mission relevance, and priority of the proposed research. JDRF encourages submission of innovative, high-risk/high-reward, field-changing research proposals to accelerate its mission.

JDRF has multiple funding mechanisms, including Research Centers, Program Projects, Clinical Investigations, Regular and Innovative Grants, and Industry Grants to build a diverse research portfolio and to provide the research community with alternative approaches to address the foundation’s mission and to provide research training opportunities to attract new talent to the field. A summary of the key features of each award type is presented in Table 1, below.

Table 1: JDRF Research Grant and Fellowship Award Mechanisms			
Award Type	Budget Cap (Annual/USD)	Duration (Years)	Letter of Intent Required?
Program Project Grant	\$660,000	3	Y*
Clinical Investigation Research Grant	\$660,000	5	Y*
Industry Discovery and Development Partnership	Open	2	Y*
Regular Research Grant	\$165,000	3	N
Innovate Grant	\$110,000	1	N
High Priority, Short-Term Bridge	\$55,000	1	N
JDRF Scholar Award	\$250,000	5	N
Career Development Award	\$150,000	5	N
Early-Career, Patient-Oriented Diabetes Research Award	\$150,000	5	N
Advanced Postdoctoral Fellowship	Up to \$90,000	3	N
Postdoctoral Fellowship	\$42,496 - \$52,492**	2	N

\* We strongly encourage applicants to contact the [JDRF Scientific Staff](#) before you submit your LOI

\*\*JDRF follows the US National Institutes of Health standards

For more detailed information about JDRF priorities and areas of research funding focus, refer to the [JDRF Research Emphasis Areas](#).

This document provides applicants with guidelines for application submission and describes the various JDRF grant types. Contact a member of JDRF [Grant Staff](#) for additional questions or assistance with the application process.

## **GENERAL INFORMATION FOR APPLICANTS**

Potential applicants should note the following:

- JDRF partners with various other national research organizations to leverage additional funds for diabetes research. The JDRF research program is intended to complement, and not to replace, funding available from other organizers. Therefore, applicants to JDRF research programs are urged to explore all potential funding sources, including other private organizations, government initiatives and consortia.
- JDRF advocacy efforts have provided additional resources for type 1 diabetes research through the US National Institutes of Health (NIH). The NIH Type 1 diabetes Special Statutory Funding Program provides research funding opportunities and access to special resources. JDRF welcomes the participation of all investigators in accessing these opportunities and applicants should describe the use of these or other resources in their proposals.
- JDRF is committed to the publication and dissemination of all information and materials developed using JDRF resources. All recipients of JDRF awards must agree to these principles and must take steps in order to facilitate availability of data and samples.

Applications for funding from JDRF must have relevance to type 1 diabetes and one or more of the JDRF research emphasis areas. Applications are accepted from any country, and there are no citizenship requirements.

## **APPLICATION REVIEW PROCESS**

Generally, applications undergo a pre-review process. For applications receiving a full review, critiques containing the reviewers' comments and a brief summary will be provided within 3 months of the review date. (Applications not recommended for full review will not receive brief written critiques.)

The Medical Scientific Review Committee (MSRC), a panel that serves for 3 years to review grant applications and participates on grant evaluations, conducts the pre-review process. To assess the scientific merit and validity of any proposal, criteria for review include:

- Scientific validity and merit of proposed research
- Technical feasibility of proposed research
- Significance of the research:
  - Impact on accelerating discovery, development, or evaluation of type 1 diabetes therapeutics
  - Potential translation to human type 1 diabetes
  - Addressing a critical research gap
- Innovation:
  - Potential for change in a paradigm
  - Potential for a seminal discovery
  - Novel approaches to solving a problem
- Ability to complete the research in the funding period

In addition to the MSRC review described above, JDRF uses a system of lay volunteer review through its Lay Review Committee (LRC). Criteria for review include:

- Relevance of the proposed research to the overall JDRF goals
- Relevance of the proposed research to specific research priorities
- Relevance of the proposed research in complementing the existing JDRF project portfolio

The Lay Review Committee places particular importance on research that may be rapidly translated into clinical applications and research deemed to have the greatest impact.

Final approval for applications is determined by the International Board of Directors.

The review process is as follows:

- 1) Applications are submitted to JDRF
- 2) MSRC reviewers are assigned by the Chair
- 3) Reviewers score the applications
- 4) Applications are “triaged” by the Chairs of both the MSRC and the LRC
- 5) LRC are assigned applications for Final Review
- 6) MSRC conduct final review
- 7) The LRC reviews the MSRC recommendations for funding and make recommendation to the Board for approval
- 8) The Board reviews the LRC final recommendations and approve or disapprove applications

Applications may be eliminated from the review process for administrative reasons (“Administrative Triage”). Applications may be administratively triaged if they do not fall into the JDRF goals/categories outlined above, or if the application is incomplete application or otherwise does not meet JDRF requirements.

Applicants will be notified in writing within 4 weeks of the review date regarding the final status of their applications. Note that status of an application will not be given by phone.

## **APPLICATION CONTENT REQUIREMENTS**

All required information must be submitted online (see below for specific instructions on how to apply). Failure to submit all required application documents online, failure to submit a budget, biosketches, or any other component of the application, or failure to adhere to the guidelines below will result in administrative triage.

### **Application Budget**

Funding requests must be submitted in US Dollars. Indirect costs must be specified on the budget page and are limited to 10% of direct costs minus equipment costs and/or subcontract costs if indirect costs are included in the budget submitted by the subcontracting organization.

### **Other Sources of Support**

Applicants must include accurate and complete information regarding all other sources of grant support from the main PI (current and pending), including title, abstract, annual and total amount of the grant, inclusive funding period, and percent effort of the applicant.

### **Other Application Content Requirements**

The application must include a complete mailing, phone, fax, and email address and must include 2 abstracts, one written for a scientific audience and one for a lay audience. The lay audience abstract must be broken out into 5 categories as outlined in the application:

- 1) Project Description
- 2) Objective
- 3) Background/Rationale
- 4) Anticipated Outcome
- 5) Relevance to Type 1 Diabetes

Each abstract category has a 3,000-character limit.

**Please note that if the guidelines outlined above are not followed, the application will be returned without review.**

### **CLINICAL STUDIES APPLICATION REQUIREMENTS**

All applications proposing research with human subjects, regardless of grant mechanism, must follow the [Guidelines for Clinical Investigations Research Proposals](#) and must include a Human Subjects Research Plan. Clinical applications without such a plan will be administratively triaged. The only exception to this are studies using only human tissue (e.g., cell lines, blood, urine, etc.) *without* ongoing patient contact.

All applicants proposing human embryonic stem cell research must read the [JDRF Policy Statement/Guidelines for the Use of Human Embryos in Stem Cell Research](#). Applicants proposing the use of human fetal tissue must read the [JDRF Policy Statement/Guidelines for the Use of Human Fetal Tissue in Research](#).

All Innovative grant applicants that propose clinical trials or other “hands on” patient-oriented research must adhere to the application deadlines posted for Regular Research Grants and Training Awards. They must also follow the [JDRF Guidelines for Clinical Investigations Research Proposals](#).

### **RESUBMISSIONS**

JDRF accepts applications resubmitted after rejection by the JDRF review committee(s) discussed above. All resubmitted applications must include:

- 1) A copy of the summary statement for the original application
- 2) A rebuttal letter (limited to two pages) addressing each of the reviewer’s concerns

These documents must be included in the “Resubmission” section of the Research Plan. Applicants that have not received an electronic copy of their summary statement should contact a member of JDRF [grant staff](#).

## STARTING A JDRF ELECTRONIC APPLICATION

Applicants applying for any of the following award types must begin their application by registering as a [proposalCENTRAL](#) user:

- Regular Research Grants
- Innovative Grants
- Postdoctoral Fellowships
- Advanced Postdoctoral Fellowships
- Career Development Awards
- Early Career Patient-Oriented Diabetes Research Awards
- Program Project Grants
- Clinical Investigations Research Grants
- Center Grants
- Scholar Awards

ProposalCENTRAL is JDRF's web-based grant management service provider. You can register and apply by clicking [here](#). If you are a JDRF Reviewer with a pre-existing registration as a Reviewer, please use the same login information to apply for a JDRF grant.

Applicants from for-profit entities should refer to the [Industry Discovery & Development Partnerships section](#) for information on JDRF funding programs for industry, and how to apply.

### ***The following award types require a Letter of Intent (LOI):***

- Program Project Grants
- Clinical Investigations Research Grants
- Center Grants

If your LOI is approved, log back on to your account on proposalCENTRAL to access the full proposal application.

## COMPLETING AN ELECTRONIC APPLICATION

You must begin your application submission process by creating a proposalCENTRAL (pC) account or by logging in with your current pC account if you have previously been issued on as either a reviewer or an applicant (see above). Once you have logged in using your pC username and password, use the following instructions as application guidelines:

- 1) Complete each of the proposal sections listed in the table of the left hand side of the screen (i.e., Title Page, Applicant/PI, Institution and Contacts, etc.). When satisfied with all of the information within a section, press "next" to save any changes and to continue to the next section.
- 2) Click on the "Proposal Attachments" link and download each proposal section template. To upload, select each proposal section one at a time as the attachment type and use the "browse" function to insert the proposal section file. Finally, click the "upload attachment button" to complete the process.
- 3) To complete the online submission, click the "submit proposal" button. You must click the "submit proposal" button to formally submit your application to JDRF.

In order to submit an application to JDRF, applicants must log onto proposalCENTRAL at <http://proposalcentral.altum.com/default.asp?GMID=16> to select the application and to complete the following:



proposalCENTRAL

[FAQ](#) || [Customer Service](#) || [Help](#) || [Login](#)  
Not Logged In

Welcome to **proposalCENTRAL**, an e-grantmaking website shared by many government, non-profit, and private grant-making organizations. If you have any questions about registration on our site, how to apply for a particular grant, or anything else we can help you with, please contact our customer support hotline at 800 875 2562 (Toll-free U.S. and Canada), +1 703 964 5840 (Direct Dial International) or by email at [pcsupport@altum.com](mailto:pcsupport@altum.com)

**First Time Users**

Click the button below to create a proposalCENTRAL user account

**REGISTER**

**Applicant Login**

Username:

Password:

**LOG IN** [Forgot your password?](#)

**Peer Reviewer Login**

[Click here](#)  
to access the online review

**Grant Opportunities - Deadlines displayed in U.S. Eastern Time**

Juvenile Diabetes Research Foundation

If you would like to check for a specific grant making organization, you may utilize the drop-down list above. To see all available opportunities, select "Show All"

Grant Maker	Programs (Click for Guidelines)	LOI Deadline	Proposal Deadline	Contact Information	FAQ
Juvenile Diabetes Research Foundation	<a href="#">Clinical Investigations Research Grant (Fall 08)</a>	6/1/2008 11:59:59 PM	9/15/2008 11:59:59 PM	<a href="#">Grants Administrator</a>	
Juvenile Diabetes Research Foundation	<a href="#">PPG Individual Core Grant</a>		9/15/2008 11:59:59 PM	<a href="#">Grants Administrator</a>	
Juvenile Diabetes Research Foundation	<a href="#">PPG Individual Project Grant</a>		9/15/2008 11:59:59 PM	<a href="#">Grants Administrator</a>	
Juvenile Diabetes Research Foundation	<a href="#">Program Project Grant (Fall 08)</a>	6/1/2008 11:59:59 PM	9/15/2008 11:59:59 PM	<a href="#">Grants Administrator</a>	
Juvenile Diabetes Research Foundation	<a href="#">Scholar Award</a>		12/1/2008 11:59:59 PM	<a href="#">Grants Administrator</a>	
Juvenile Diabetes Research Foundation	<a href="#">Islet Transplantation Program</a>	10/15/2008 11:59:59 PM	12/30/2008 11:59:59 PM	<a href="#">Grants Administrator</a>	

1. Fill out each of the proposal sections listed in the table of the left hand side of the screen including (e.g. [Title Page](#), [Applicant/PI](#), [Institution and Contacts](#), etc.) When satisfied with all of the information within a section; press next to save any changes and proceed to the next section.

Deadline: 4/23/2008 11:59:59 PM (U.S. Eastern Time)

Title Page

The submission deadline has passed, contact the grantmaker to request an extension.

---

Enter a title for your application, then press Save.  
Press Next to save any changes and go to the next proposal section.

\* Project Title  Do not exceed 75 characters.

Title Page

The submission deadline has passed, contact the grantmaker to request an extension.

**Proposal Sections**  
Click name below to go to that section.

- 1) [Title Page](#)
- 2) [Download Templates & Instructions](#)
- 3) [Enable Other Users to Access this Proposal](#)
- 4) [Applicant/PI](#)
- 5) [Institution & Contacts](#)
- 6) [Key Personnel](#)
- 7) [Project Description/Abstracts](#)
- 8) [Budget Period Detail](#)
- 9) [Budget Summary](#)
- 10) [Other Support](#)
- 11) [Organization Assurances](#)
- 12) [Proposal Attachments](#)
- 13) [Specific Aims](#)
- 14) [Validate](#)
- 15) [Signature Page\(s\) - Upload NOT required](#)

**Support Links**

2. Click on the [Proposal Attachments](#) link and download each proposal section template. To upload, select each proposal section one at a time as the attachment type and browse your computer to insert the proposal section file. Finally, click the upload attachment button to complete the process.

## ProposalCENTRAL TEMPLATES

### Using Templates

The Proposal Attachments section of the application contains downloadable files. The files include templates and instruction documents. Click the “download” link to save a template to your computer. You will complete each template offline. Use MS Word or MS Excel (depending on the template) to complete the template documents, then convert each file to PDF and upload the completed attachment files to your online application (see below for more information).

Some of the files you will download are required attachments. All required attachments will be indicated as such. Once you upload a completed required template, the template name will display in the “Current List of Uploaded Attachments” menu. The “Validate” link, located in the gray navigation menu and available from every online page of the online application, can also serve as a tool for you to check to ensure that at least one of each of the required attachments is included in your application.

### Uploading Completed Templates

Once you have converted your application template to PDF, you must then upload the file(s) to your online application. Follow the following steps:

- Open your online application and go to the page from which you downloaded the template
- Enter your own description of the file in the “Describe Attachment” field
- Choose from the dropdown list of attachment types (e.g., Biosketch, Other Support)
- Click on the “Browse” button and choose your PDF, then upload the attachment

The file is now attached to the application and should now be listed in the “Uploaded Attachment” section. Two links are available in each row of an uploaded attachment: DEL (delete) and SHOW. “Del” allows you to delete the file, if necessary, and “show” opens the uploaded file. It is strongly recommended that you open and review your uploaded file.

If, for any reason, you wish to modify the file, make the revisions in the original document (offline), convert the updated file to PDF and attached the revised file to the application. Delete previously submitted versions of the file.

## VALIDATION AND FINAL SUBMISSION

To submit the final application, you must first validate your application to ensure that all required files are attached and that all required entries on all pages of the application have been completed as required. Click the “Validate” link to complete this process.

Click the “Submit Proposal” button to formally submit your completed application to JDRF.

**SPECIAL NOTE:** JDRF no longer requires signed Signature Pages. The final submission of your proposal to JDRF (via proposalCENTRAL) automatically indicates to JDRF that the PI and his/her administrative and financial officials, sponsors, and/or department heads certify that the statements within their JDRF proposal are true, complete, and accurate to the best of their knowledge, and accept the obligation to comply with JDRF’s [terms and conditions](#) if the grant is awarded as a result of

the application. It further certifies that they are aware that any false, fictitious, or fraudulent statements or claims may subject the PI and the PI's officials to criminal, civil, or administrative penalties.

## **APPLICATION FORMATTING REQUIREMENTS**

### **File Size**

Limit the file size of each uploaded attachment to 3-4 MB.

### **Images and Text Formatting**

- 1) Do not use text boxes
- 2) When incorporating figures into the text of your application document(s), follow these steps:
  - a. Save your figures as individual .jpg or .gif files. Make sure your figures are not inserted into a text box. Do not use other graphic file types (e.g., .tif)
  - b. In your MS Word application document, select "Insert→Picture→From File" in the "Insert" menu. Select the .jpg file you created, and click on the "Insert" button.
- 3) Type size limitations must be observed throughout the application. Use 10-point size font only. Figure legends, footnotes, and aspects of charts and tables may be smaller in font size, but must still be clear and legible
- 4) Margins, in all directions, must be at least ½ inch
- 5) Be consistent with font styles and indentation
- 6) Research Plan page limits do not include figures, charts, and tables, except where noted.

### **Other Requirements**

- 1) Use English only and avoid jargon and unusual abbreviations
- 2) Do not include your social security number or passport number in your JDRF application

## SECTION 2: GRANT MECHANISMS DESCRIPTIONS

### REGULAR GRANTS

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#### REGULAR RESEARCH GRANT

##### DESCRIPTION

The purpose of the Regular Research Grant mechanism is to provide investigators with support to explore the feasibility and development of proposals that are considered to be on the leading edge of diabetes research and that address the [JDRF research emphasis areas](#). Proposals that have the potential to impact the current state of diabetes research or that clearly lead to avenues of therapeutic benefit are major considerations for the Regular Research Grant. Also of merit are exploratory proposals that may or may not have sufficient preliminary data but have a sound research development plan that is considered to be of high priority to JDRF. The Regular Research grant mechanism is specifically intended to support innovative proposals that can be developed to a level of maturity where generated data strengthens future research project grant applications for ongoing support.

##### ELIGIBILITY

Applications may be submitted by domestic and foreign non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government. Applicants must hold an MD, DMD, DVM, PhD, or equivalent and have a faculty position or equivalent at a college, university, medical school, or other research facility. There are no citizenship requirements for this program. To assure continued excellence and diversity among applicants and awardees, JDRF welcomes applications from all qualified individuals and encourages applications from persons with disabilities, women, and members of minority groups underrepresented in the sciences.

Please note that applications coming from for-profit entities should not be submitted under a Regular Research Grant – please refer to the [Industry Discovery & Development Partnerships section](#) of this document for more information.

**Note: if your project involves clinical studies, click [here](#).**

##### PROPOSAL

All applications must be completed using the templates provided on the proposalCENTRAL website. See the [proposalCENTRAL templates](#) and the [Applications Guidelines](#) sections for specific requirements.

##### RESEARCH PLAN

The research plan may not exceed 10 pages, not including figures and tables. The research plan must be organized as follows: a) Specific Aims; b) Background and Significance of this work to Type 1 Diabetes; c) Preliminary Studies/Progress Report (for competitive renewal); d) Research Design and Methods; e) Literature Cited (no page limit).

All information in items a through d above must be incorporated in the 10-page limit, without exception. Applications with research plans exceeding the page limit will not be reviewed.

## **REVIEW CONSIDERATIONS**

Applications will be evaluated in accordance with the criteria described below. Evaluations will be competitive and performed by an appropriate peer and lay review group convened by JDRF (see the [Application Review Process section](#), above, for more information). The review criteria include:

- 1) Potential to generate proof of principle for new approaches to unsolved scientific problems related to type 1 diabetes
- 2) Relevance to the objectives of JDRF
- 3) Scientific, technical, or medical significance of the research proposal
- 4) Innovation
- 5) Appropriateness and adequacy of the experimental approach and methodology
- 6) Qualifications and research experience of the principal investigators and collaborators
- 7) Availability of resources and facilities necessary for the project
- 8) Appropriateness of the proposed budget in relation to the proposed research

## **TERMS OF THE AWARD**

JDRF Regular Research Grants will be supported for a maximum of USD 165,000 total costs per year for a period of up to 3 years. Indirect costs cannot exceed 10 percent of direct costs. In general, these grants are not renewable after 3 years. However, in rare instances (e.g., where NIH funding is not available) support beyond 3 years will be considered based on a competitive review of the accomplishments and future plans.

An annual progress report will be due 60 days prior to the anniversary date of the award, except in the final year, in which a final progress report is due within 60 days following the close of the award.

## INNOVATIVE GRANT

Note: if your project involves clinical studies, click [here](#).

### DESCRIPTION

JDRF provides “seed” funding for highly innovative research with potential significant impact on accelerating the mission of JDRF. The innovative research should have the potential for a change in the current paradigm or conventional wisdom or to lead to a seminal discovery or to be groundbreaking. Preliminary data is not required in the proposal but the underlying premise, goal, or hypothesis must be plausible and the proposal must be focused with a well defined goal.

These grants provide one year of support for a maximum of \$100,000 in direct costs and indirect costs of 10%, for a total of \$110,000. These grants are not renewable. Please note that applications exceeding this time limit and amount may be considered under exceptional circumstances. For more information contact the appropriate member of [JDRF staff](#).

These grants will be evaluated based on the following criteria:

- Is the proposed research highly innovative?
- Is the underlining premise, goal or hypothesis plausible?
- Does the proposed research have the potential for high impact on the mission of JDRF?
- Can the proposed research be completed in one year?

In the application, the investigator must specifically address how the proposal is innovative and clearly state the problem, hypothesis, methodology, and possible outcomes. The research plan has a strict **3-page limit**.

### ELIGIBILITY

Applications may be submitted by domestic and foreign non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government. Applicants must hold an M.D., D.M.D., D.V.M., Ph.D., or equivalent and have a faculty position or equivalent at a college, university, medical school, or other research facility. Please note that applications coming from for-profit entities should NOT be submitted here. Please refer to [Industry Discovery & Development Partnerships](#) for information on JDRF funding programs for industry and how to apply. There are no citizenship requirements for this program. To assure continued excellence and diversity among applicants and awardees, JDRF welcomes applications from all qualified individuals and encourages applications from persons with disabilities women and members of minority groups underrepresented in the sciences.

### PROPOSAL AND SUBMISSION

All applications must be completed using the templates provided on the proposalCENTRAL Web site. (For more information click here: Application Requisites & Tips section) Proposal section templates in MS Word should be typewritten, single-spaced, and in typeface no smaller than **10-point font** and have no more than six vertical lines per vertical inch. Margins, in all directions, must be at least ½ inch. Complete information should be included to permit review of each application without reference to previous applications.

All applications must be completed using the templates provided on the [proposalCENTRAL website](#). Click here for more information on specific [template/proposal requirements](#).

## RESEARCH PLAN

The innovative grant research plan may not exceed 3 pages and preliminary studies are not required. Please note that the 3-page limit includes narrative items A through D as described below.

Applications with research plans exceeding the page limit will not be reviewed. The research plan must be organized as follows: A) Hypothesis, Goal, Specific Aims; B) Background, Innovativeness, and Potential Significance to Type 1 Diabetes; C) Preliminary Studies (if available); D) Research Design and Methods; E) Literature Cited (no page limit).

**NEW:** Projects with significantly higher cost or requiring greater than one year of funding may still be considered for an Innovative Grant at the discretion of JDRF staff.

**If you believe that your Innovative project requires a greater budget or funding period, please contact [JDRF Program Staff](#) in the relevant area to discuss possible options for submission.**

### Examples might include:

- Research that requires collaborative or multi-disciplinary approaches to address a single hypothesis
- Research that requires high-cost resources, e.g. costly reagents for genomics/ proteomics studies
- Studies that employ large-animal models or animal models that require lengthy development or distant endpoints

# CONFERENCE GRANTS

## DESCRIPTION

JDRF supports scientific meetings, conferences, and workshops relevant to its mission. Applications for conference support are accepted for consideration throughout the year.

## ELIGIBILITY

Each criterion will be considered in the context of how it relates to JDRF research priorities:

- 1) How does the meeting/conference relate to JDRF goals?
- 2) What is the format and agenda?
- 3) What is the need for the meeting/conference?
- 4) What is the timeliness of the meeting/conference?
- 5) What are the qualifications of the organizers and proposed participants?
- 6) What is the past performance of the meeting/conference (when applicable)?
- 7) How appropriate is the meeting site?
- 8) How appropriate is the budget?

## APPLICATION

Conference Grant applications are accepted for consideration throughout the year. Applicants will be notified in writing within one month after completion of the review process.

### *Requests of Less than \$10,000*

The appropriate representative of the applicant organization must provide a letter of intent, draft agenda, and a budget. The letter should address the criteria summarized above. The JDRF review panel may request supplemental information. Letters of intent and accompanying documents should be sent to:

Nadia Jenkins  
Juvenile Diabetes Research Foundation  
120 Wall Street, 19<sup>th</sup> Floor  
New York, NY 10005 USA  
or  
[Scientific Program Staff](#)

### *Request of \$10,000 or More*

A formal JDRF application must be submitted by a representative of the applicant organization. The application includes the [application form for funding](#) and must also include the following:

- 1) Scientific Abstract
- 2) Lay Abstract
- 3) Meeting Organizers
- 4) Budget
- 5) Dissemination of Information
- 6) Conference Speakers
- 7) Conference Program
- 8) JDRF Criteria

More specific information relating to the 8 required items above can be found on the [form for funding](#).

Email the application to:  
[Scientific Program Staff](#)

#### **OTHER REQUIREMENTS**

- 1) In general, complimentary registration for a designated member of JDRF staff, or JDRF guests, is required for JDRF sponsorship of a meeting.
- 2) JDRF sponsorship must be acknowledged in all publicity and in the program for the meeting and any proceedings or publications resulting from the meeting.
- 3) Copies of proceedings or publications resulting from the meeting must be provided to JDRF.
- 4) JDRF reserves the right to post the meeting notice/agenda as well as other information relating to the meeting on the JDRF website. In addition, the application is required to provide a brief report, written in lay terms, after the meeting for posting on the JDRF website.

## TRAINING GRANTS

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### POSTDOCTORAL FELLOWSHIPS

#### DESCRIPTION

Postdoctoral fellowships are designed to attract qualified, promising scientists entering their professional career in the diabetes research field. The applicant is required to work with a sponsor who can provide a training environment conducive to beginning a career in type 1 diabetes-relevant research. At the time of activating the award, the applicant must have a doctoral degree (PhD, MD, DMD, DVM), or the equivalent from an accredited institution and must not be simultaneously serving an internship or residency.

#### ELIGIBILITY

##### *Applicant*

The fellowships are intended for those in a relatively early stage of their career. Ordinarily, their first degree (PhD, MD, DMD, DVM, or equivalent) will have been received no more than five years before the fellowship. Since this program is targeted to those who would benefit from postdoctoral research training in preparation for later faculty appointments, applicants may not have faculty appointments.

There are no citizenship requirements for this program. To assure continued excellence and diversity among applicants and awardees, JDRF welcomes applications from all qualified individuals and encourages applications from persons with disabilities women and members of minority groups underrepresented in the sciences.

##### *Sponsor*

The applicant must be sponsored by an investigator who is affiliated full-time with an accredited institution and who agrees to supervise the applicant's training. The sponsor does not necessarily need to have a background in diabetes, but the research project must be type 1 diabetes-related.

##### *Location*

Fellowship research may be conducted at foreign and domestic, for-profit and nonprofit, and public and private organizations—such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government.

#### PROPOSAL

All applications must be completed using the templates provided on the [proposalCENTRAL website](#). Click here for more information on specific [template/proposal requirements](#).

#### RESEARCH PLAN

The research plan should be suitable for a two-year postdoctoral training period. The project should ask a specific and substantive question and be relevant to JDRF's mission. Extensive discussion between the applicant and the proposed mentor is expected in order to identify an appropriate research project—one that is up-to-date, instructive, and suited to a two-year fellowship period.

The postdoctoral fellowship research plan may not exceed 7 pages not including figures and tables. Please note that the 7-page limit includes narrative items a through d, as described below. Applications with research plans exceeding the page limit will not be reviewed. The research plan must be organized as follows: a) Specific Aims, b) Background and Significance of this work to Type 1 diabetes (provide a brief historical background of your proposed research, including major findings by you and/or others in relevant fields. Explain why you have chosen this problem), c) Preliminary

Results (if available), d) Research Designs and Methods. Describe, in detail, plans for solving problems, hypothesis, methodology, expected results, experimental subjects, controls, potential pitfalls and the rationale for the chosen approach), e) Other aspects (formal and informal) of the program that will contribute to the total training environment (examples include, but are not limited to, clinical experience with diabetic patients, interaction with senior professional with expertise in diabetes, participation in staff conferences, teaching, consultation, etc.), f) List any planned coursework, g) List pertinent literature references (no page limit). *All information in items a through d must be incorporated into the 7-page limit without exception.*

In addition, a Future Career Plans statement and a Training Plan statement must be included at the end of the Research Plan section (see below).

### **FUTURE CAREER PLANS STATEMENT**

The applicant must include a statement of career goals and indicate the relevance of these goals to type 1 diabetes-related research.

### **SPONSOR APPLICATION REQUIREMENTS**

The sponsor must provide a biographical sketch, a list of previous trainees, and a statement of the plan for training the applicant. This statement must outline a detailed training program for the applicant as well as confirm the availability of facilities to conduct the research project. The sponsor must also include accurate and complete information regarding all other sources of grant support (current and pending), including title, abstract, annual and total amount of grant, inclusive funding period, and percentage effort of the applicant.

### **RECOMMENDATION REFERENCES**

Three (3) recommendation references assessing the scientific abilities and potential of the applicant must be submitted. Please note that the recommendation references are confidential and will not be released to the applicant. *The recommendation references must be submitted directly to proposalCENTRAL by the referee. Please note applications will not be validated until all references are submitted.* Sponsors cannot be references, but should complete the Training Plans section of the application.

### **EVALUATION**

Fellowships will be awarded on the basis of the applicant's previous experience, academic record, the caliber of the proposed research, and the quality of the mentor, training program, and environment. The relevance of the proposal to the cause, cure, treatment, and/or prevention of diabetes and its complications will also be considered.

The applicant's professional ability and promise for a research career in type 1 diabetes will hold the highest priority in selection and will be assessed on the basis of the letters of recommendation, career plans, prior clinical and research training, academic transcripts, and the mentor's endorsement. Location in a department that will provide a stimulating research environment is an additional factor that will be considered in evaluating applicants.

### **TERMS OF AWARD & STIPENDS**

Awards are for two years, assuming satisfactory progress. The fellowship term is 12 months for each fellowship year, and fellows must devote 100% of their effort to the project outlined in the fellowship application. Recipients of the JDRF postdoctoral fellowship award cannot hold another postdoctoral fellowship at the same time.

Award amounts are based on years of relevant postdoctoral experience effective March 1, 2006 (see Table 2, below). There are no indirect costs allowed for fellowships and JDRF will make no deductions for income tax, Social Security, etc. A research allowance of USD 5,500 is aimed at providing the fellow with funds to enrich their training experience and can be used for travel to scientific meetings (up to USD 2,000/year), journal subscriptions, books, training courses etc. They are not to be used for laboratory supplies or equipment. Personal computer costs are allowed. Health insurance costs are permissible. The award is renewable for a second year pending submission and approval of a renewal application and progress report.

<b>Table 2: Postdoctoral Fellowship Allowances</b>			
<b>Years</b>	<b>Stipend</b>	<b>Research Allowance</b>	<b>Total</b>
0	\$36,996	\$5,500	\$42,496
1	\$38,976	\$5,500	\$44,476
2	\$41,796	\$5,500	\$47,296
3	\$43,428	\$5,500	\$48,928
4	\$45,048	\$5,500	\$50,548
5	\$46,992	\$5,500	\$52,492

## ADVANCED POSTDOCTORAL FELLOWSHIPS

### DESCRIPTION

The Advanced Postdoctoral Fellowship program is designed to attract qualified and promising health scientists, to provide an opportunity to receive full time research training, and to assist these promising individuals in transitioning from a fellowship to an independent (faculty-level) position. JDRF envisions the 3-year award term as a period in which fellows will receive critical research training that will position them to work at the leading edge of their chosen field. An additional, optional 1-year “transition” award will further assist fellows to proceed to independent faculty or research appointments and will serve as a bridge between the fellowship and independent competitive research funding. During the fellowship phase, the applicant is required to work with a sponsor who can provide a training environment conducive to beginning a career in diabetes-relevant research. At the time of activating the award, the applicant must have a doctoral degree (PhD, MD, DMD, DVM, or equivalent) from an accredited institution and must not be simultaneously serving an internship or residency.

### ELIGIBILITY

#### *Applicant*

The fellowships are intended for those in a relatively early stage of their career. Generally, their first degree (PhD, MD, DMD, DVM, or equivalent) will have been received no more than 5 years before the fellowship. Applicants who have completed 1-3 years of postdoctoral training and now show extraordinary promise may wish to apply for this “advanced” award. Alternatively, exceptionally qualified and talented individuals are encouraged to apply at the beginning of their careers. This program is targeted to those who would benefit from postdoctoral research training in preparation for later faculty appointments (therefore, applicants may not have faculty appointments). There are no citizenship requirements for this program. To assure continued excellence and diversity among applicants and awardees, JDRF welcomes applications from all qualified individuals and encourages applications from persons with disabilities women and members of minority groups underrepresented in the sciences.

#### *Sponsor*

The applicant must be sponsored by an investigator who is affiliated full-time with an accredited institution and who agrees to supervise the applicant’s training. The sponsor does not necessarily need to have a background in diabetes, but the research project must be diabetes-related.

#### *Location*

Fellowship research may be conducted at foreign and domestic, for-profit and nonprofit, and public and private organizations—such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government.

### PROPOSAL

All applications must be completed using the templates provided on the [proposalCENTRAL website](#). Click here for more information on [specific template/proposal requirements](#).

### RESEARCH PLAN

The advanced postdoctoral fellowship research plan may not exceed 7 pages not including figures and tables. Please note that the 7-page limit includes narrative items a through d, as described below. Applications with research plans exceeding the page limit will not be reviewed. The research plan must be organized as follows: a) Specific Aims, b) Background and Significance of this work to Type 1 diabetes (provide a brief historical background of your proposed research, including major findings by

you and/or others in the relevant field. Explain why you have chosen this problem), c) Preliminary Results (if available), d) Research Designs and Methods. Describe, in detail, plans for solving problems, hypothesis, methodology, expected results, experimental subjects, controls, potential pitfalls and the rationale for the chosen approach), e) Other aspects (formal and informal) of the program that will continue to the total training environment (examples include, but are not limited to, clinical experience with diabetic patients, interaction with senior professional with expertise in diabetes, participation in staff conferences, teaching, consultation, etc.), f) List any planned coursework, g) List pertinent literature references (two-page limit). *All information in items a through d must be incorporated into the 7-page limit without exception.*

In addition, a Future Career Plans statement and a Training Plan statement must be included at the end of the Research Plan section (see below).

### **FUTURE CAREER PLANS STATEMENT**

The applicant must include a statement of career goals and indicate the relevance of these goals to type 1 diabetes-related research.

### **SPONSOR APPLICATION REQUIREMENTS**

The sponsor must provide a biographical sketch, list of previous trainees, and a statement of the plan for training the applicant. This statement must outline a detailed training program for the applicant as well as confirm the availability of facilities to conduct the research project. The sponsor must also include accurate and complete information regarding all other sources of grant support (current and pending), including title, abstract, annual and total amount of grant, inclusive funding period, and percentage effort of the applicant.

### **RECOMMENDATION REFERENCES**

Three (3) recommendation references assessing the scientific abilities and potential of the applicant must be submitted. Please note that the recommendation references are confidential and will not be released to the applicant. *The recommendation references must be submitted directly to proposalCENTRAL by the referee. **Please note applications will not be validated until all references are submitted.*** Sponsors cannot be references, but should complete the Training Plans section of the application.

### **EVALUATION**

Fellowships will be awarded on the basis of the applicant's previous experience, academic record, the caliber of the proposed research, the quality of the mentor, training program, and environment, and the applicant's potential to obtain an independent research position in the future. The relevance of the proposal to the cause, cure, treatment, and/or prevention of diabetes and its complications will also be considered. The applicant's professional ability and promise for a research career in type 1 diabetes will hold the highest priority in selection and will be assessed on the basis of the letters of recommendation, career plans, prior clinical and research training, academic transcripts, and the mentor's endorsement. Location in a department that will provide a stimulating research environment is an additional factor that will be considered in evaluating applicants.

### **TERMS OF AWARD & STIPENDS**

Awards will be made for a duration of up to 3 years, assuming satisfactory progress. The fellowship term is 12 months for each fellowship year, and fellows must devote 100 percent of their effort to the project outlined in the application.

Budgets up to USD 90,000 per year for up to 3 years may be requested. The stipend request must be consistent with the amounts shown below (see Table 2) based on years of relevant postdoctoral experience. Salary support for additional staff is not allowable.

There are no indirect costs allowed for fellowships and JDRF will make no deductions for income tax, Social Security, etc. Funds in excess of the stipend, up to a total budget of \$90,000 per year, can be used for travel to scientific meetings (up to \$2000/year), journal subscriptions, books, training courses, laboratory supplies, or equipment (in Year 1 only). The purchase of a personal computer is allowed (up to \$2000) only during Year 1 of the award. Health insurance costs are permissible. The award is renewable for up to two additional years pending submission and approval of a renewal application.

<b>Table 2: Advanced Postdoctoral Fellowship Stipends</b>	
<b>Years</b>	<b>Stipend</b>
0	\$36,996
1	\$38,976
2	\$41,796
3	\$43,428
4	\$45,048
5	\$46,992
6	\$48,852
7+	\$51,036

### **TRANSITION AWARD**

To assist the awardee's advancement to a faculty position, the advanced postdoctoral fellowship carries an optional "transition" year in which the awardee may request funding support in their first year as a faculty member of an academic institution. To apply for the transition year, awardees must provide a letter of institutional commitment and faculty appointment along with a satisfactory progress report and abbreviated research plan for the transitional year. The Transition Award can be requested in an amount up to \$110,000 total costs for 1 year. Indirect costs (excluding equipment) cannot exceed 10 percent. The Transition Award can be requested at any time during the 3-year fellowship period after a faculty appointment has been obtained.

## CAREER DEVELOPMENT AWARDS

### DESCRIPTION

JDRF fosters the development and productivity of the best and the brightest established independent researchers who will bridge the gap between the bench and bedside. The primary purpose of the Career Development Award is to attract qualified and promising scientists early in their faculty careers and to give them the opportunity to establish themselves in areas that reflect the [JDRF research emphasis areas](#).

In the five-year term of the award, awardees will focus their research efforts on a subject directly related to JDRF mission goals and research priorities, and position themselves to work at the leading edge of type 1 diabetes research. These awards are designed to assist exceptionally promising investigators. Although JDRF is especially interested in fostering careers in clinical investigation, Career Development Awards may emphasize either basic or clinical topics.

### ELIGIBILITY

The Career Development Award is intended for individuals in a relatively early stage of their career. Ordinarily, their first degree (MD, PhD, DMD, DVM, or equivalent) will have been received at least three but not more than seven years before the award. The applicant must hold an academic faculty-level position (including assistant professor or equivalent) at the time of the application, at a university, health science center, or comparable institution with strong, well-established research and training programs for the chosen area of interest.

There are no citizenship requirements for this program. To assure continued excellence and diversity among applicants and awardees, JDRF welcomes applications from all qualified individuals and encourages applications from persons with disabilities women and members of minority groups underrepresented in the sciences.

Career Development Award research may be conducted at foreign and domestic, for-profit and nonprofit, and public and private organizations—such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government.

### PROPOSAL

All applications must be completed using the templates provided on [the proposalCENTRAL website](#). Click here for more information on [specific template/proposal requirements](#).

### RESEARCH PLAN

The Career Development Award research plan should describe a five-year project. The project should address a specific and substantive question that is relevant to the JDRF mission. The research plan may not exceed 10 pages, not including figures and tables. Please note that the 10-page limit includes narrative items a through d as described below. Applications with research plans exceeding the page limit will not be reviewed. The research plan must be organized as follows: a) Specific Aims; b) Background and Significance of this work to Type 1 Diabetes; c) Preliminary Studies (if applicable); d) Research Design and Methods; d) Literature Cited (no page limit). *All information in items a through d must be incorporated in the 10-page limit without exception.*

In addition, a Future Career Plans statement must be included at the end of the Research Plan section (see below).

## **FUTURE CAREER PLANS STATEMENT**

The applicant must include a statement of career goals and indicate the relevance of these goals to type 1 diabetes-related research.

## **RECOMMENDATION REFERENCES**

Three (3) recommendation references assessing the scientific abilities and potential of the applicant must be submitted. Please note that the recommendation references are confidential and will not be released to the applicant. The recommendation references must be submitted directly to proposalCENTRAL by the referee. Please note applications will not be validated until all references are submitted.

## **INSTITUTIONAL ASSURANCE**

The applicant's institution must, through the departmental supervisor, provide assurance of an academic commitment to the applicant and to the research project. This Department Head Statement must be included in the Supporting Documents section of the Proposal Narrative.

## **EVALUATION**

Awards will be made on the basis of the applicant's perceived ability and potential for a career in type 1 diabetes research, the caliber of the proposed research, and the quality and commitment of the institution. The applicant's professional ability and promise will hold the highest priority in selection and will be assessed on the basis of items such as letters of recommendation, publications, career plans, and prior clinical and research training.

## **TERMS OF THE AWARD**

The award is up to USD 150,000 per year, including indirect costs. These funds may be used for a research allowance, which can include a technician, supplies, equipment and travel up to USD 2000 per year. The awards are renewable pending satisfactory progress up to a maximum of four years. Salary for additional research personnel is permitted. Requests for equipment, in years other than the first year, must be strongly justified. Salary requests must be consistent with the established salary structure of the applicant's institution. Indirect costs (excluding equipment) may not exceed 10% of subtotal direct costs. Please see JDRF's [budget guidelines](#) for more details.

Awardees will be required to provide a progress report at the end of each funding year. Awards are renewable each year for a maximum of four years after submission and approval of a renewal application. Awardees must spend at least 75% of time and effort on type 1 diabetes-related research projects during the period of the award.

## EARLY CAREER PATIENT-ORIENTED DIABETES RESEARCH AWARD

### DESCRIPTION

The JDRF Early Career Patient-Oriented Diabetes Research Award will provide crucial support to investigators who plan to pursue a career in diabetes-related clinical investigation. These prestigious awards are made in the later stages of training and include the ability for recipients to transition to independent faculty or research appointments. The award has a five-year term.

### ELIGIBILITY

#### *Applicant*

The successful candidate will have an MD or MD-PhD, hold an appointment or joint appointment in a subspecialty of clinical medicine, and conduct human clinical research. In exceptional circumstances, non-MD candidates will be considered if their work is likely to contribute significantly to a clinical outcome. The candidate must hold an appointment or joint appointment in a clinical department.

For the purposes of this award, clinical research is defined as research conducted with human subjects for which the investigator directly interacts with the subjects. Areas of relevant research can include (but are not limited to): 1) mechanisms of human disease; 2) therapeutic interventions; 3) clinical trials; 4) the development of new technologies.

There are no citizenship requirements for this program. To assure continued excellence and diversity among applicants and awardees, JDRF welcomes applications from all qualified individuals and encourages applications from persons with disabilities, women, and members of minority groups underrepresented in the sciences.

#### *Sponsor*

The applicant must be sponsored by an investigator who is affiliated full-time with an accredited institution, who pursues clinical research, and who agrees to supervise the applicant's training. The sponsor does not necessarily need to have a background in diabetes, but the research project must be type 1 diabetes-related and patient-oriented.

#### *Location*

Research may be conducted at foreign and domestic, for-profit and nonprofit, and public and private organizations-such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government.

### PROPOSAL

All applications must be completed using the templates provided on the [proposalCENTRAL website](#). Click here for more information on specific [template/proposal requirements](#).

### RESEARCH PLAN

The early career patient-oriented research plan may not exceed 10 pages, not including figures and tables. Please note that the 10-page limit includes narrative items a through d as described below. Applications with research plans exceeding the page limit will not be reviewed. The research plan must be organized as follows: a) Specific Aims; b) Background and Significance of this work to Type 1 Diabetes; c) Preliminary Studies (if applicable); d) Research Design and Methods; e) Literature Cited (no page limit). *All information in items a through d must be incorporated in the 10-page limit without exception.*

In addition, a Future Career Plans statement and a Training Plans statement must be included at the end of the Research Plan section (see below).

### **FUTURE CAREER PLANS STATEMENT**

The applicant must include a statement of career goals and indicate the relevance of these goals to type 1 diabetes-related research. The future career plans statement should detail the applicant's plan for career development as an independent investigator. Topics to be discussed by the applicant may include: how much of the applicant's time will be protected for research; how the proposed research will contribute to the applicant's independent career; an expected timeline for obtaining an independent position, if the applicant is not already at that stage; how the JDRF award will contribute to the applicant's future career plans; and any other planned formal or informal activities that will aid the applicant in establishing an independent research career. If the research proposed in the application is part of a larger research program or trial, the applicant should clearly define his/her role in the project and explain how their efforts on the project will lead to independence.

### **SPONSOR APPLICATION REQUIREMENTS**

The sponsor must provide a biographical sketch, list of previous trainees, and a statement of the plan for training the applicant. This statement must outline a detailed training program for the applicant as well as confirm the availability of facilities to conduct the research project. The sponsor's statement should address plans for supervision, guidance, counseling, or other formal or informal training of the applicant.

The sponsor must also include accurate and complete information regarding all other sources of grant support (current and pending), including title, abstract, annual and total amount of grant, inclusive funding period, and percentage effort of the applicant.

### **RECOMMENDATION REFERENCES**

Three recommendation references assessing the scientific abilities and potential of the applicant must be submitted. Please note that the recommendation references are confidential and will not be released to the applicant. The recommendation references must be submitted directly to [proposalCENTRAL](#) by the referee. Please note applications will not be validated until all references are submitted. Sponsors cannot be references, but should complete the Training Plans section of the application.

### **INSTITUTIONAL ASSURANCE**

Institutions should provide detailed evidence that their facilities are adequate for the proposed research, and that they have made a tangible commitment to fostering the career-development of clinical investigators conducting patient-oriented research. A Department Head Statement outlining this must be included in the Supporting Documents section of the Proposal Narrative.

### **EVALUATION**

Awards will be made to applicants who have demonstrated superior scholarship and show the promise for future achievement in clinical research, particularly in those areas that require the unique training of a clinical investigator.

The initial step in the evaluation procedure for this award will be screening of the applicant by a panel of distinguished scientists. The panel, convened by JDRF, will evaluate each candidate's qualifications and potential to conduct innovative patient-oriented research, as well as the quality and originality of the proposed research and its potential to advance clinical care. The panel will also consider the institutional environment, including laboratory and patient facilities that will be available to

the awardee. The final selection of the awardees will be made by JDRF, based on the evaluations of the review panel.

#### **TERMS OF THE AWARD**

Awardees will be required to provide an annual progress report. Awards are renewable for a maximum of four years. Awardees must devote at least 75% of professional effort to the conduct of type 1 diabetes-related clinical research during the period of the award.

Awards are in the amount of up to USD 150,000 total costs per year. Up to USD 75,000 of this may be requested for research allowance, which can include a technician, supplies, equipment, and travel up to USD 2,000 per year. Salary request must be consistent with the established salary structure of the applicant's institution, and equipment in years other than the first must be strongly justified.

Indirect costs (excluding equipment) cannot exceed 10%. Please see JDRF's [budget guidelines](#) for details.

## SPECIAL GRANTS

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### PROGRAM PROJECT GRANT

**Note:** Only applicants who have an approved JDRF Letter of Intent (LOI) for a Program Project Grant (PPG) may submit applications under this category. If you submit a PPG application without a prior LOI approval, your application will not be considered.

#### DESCRIPTION

JDRF Program Projects provide a mechanism to stimulate new collaborations between clinical and basic scientists and/or between scientists from diverse backgrounds as a means to conceive and develop new approaches to persistent obstacles to progress along the various paths to a cure for type 1 diabetes and its complications. JDRF Program Projects must have a central theme highly relevant to the priority areas of research for JDRF. Program Projects should have a set of clearly defined goals that can be met within a 3-year period. In most cases, JDRF Program Projects will focus on basic or pre-clinical research that seeks to impact the treatment or prevention of type 1 diabetes and its complications. However, clinical studies meeting the other criteria for program projects will be considered.

Program Projects should be composed of 3-6 projects and 1-3 cores, with component projects being highly interactive and benefiting from the use of common cores. In general, the component projects will have interdependent outcomes. An overall Program Project principal investigator is required. Generally, administration of the Program Project will rely on mutually agreed-upon leadership and common consent of the individual project principal investigators. In many instances, an administrative core will not be necessary, and any budget requests for administrative support must be strongly justified in the Program Project Grant application.

#### ELIGIBILITY

Applicants must hold an MD, DMD, DVM., PhD, or equivalent and have a faculty position or equivalent at a college, university, medical school, company, or other research facility.

Applications may be submitted by domestic and foreign non-profit organizations, public and private, such as colleges, universities, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government. Ordinarily, for-profit organizations will not be considered, except under special circumstances. See the [Industry Discovery & Development Partnerships](#) section for a description of special programs for for-profit entities.

There are no citizenship requirements for this program. To assure continued excellence and diversity among applicants and awardees, JDRF welcomes applications from all qualified individuals and encourages applications from persons with disabilities, women, and members of minority groups underrepresented in the sciences.

**Note:** if your project involves clinical studies, click [here](#).

#### LETTER OF INTENT

A letter of intent is required. Prospective applicants should submit a letter of intent on-line via the [proposalCENTRAL website](#). The LOI template provided on the proposalCENTRAL website must be used to complete the application.

Applicants will be notified four (4) weeks after the LOI deadline date if they have been approved to continue forward to submit a full application.

## **APPLICATION**

**Note:** Upon approval of the LOI, only the PPG Overview application will become automatically available. The Principal Investigators of individual Projects & Cores must complete separate online applications on the [proposalCENTRAL website](#) for each PPG Project and Core.

If the applicant's LOI has been approved by JDRF, the applicant will be invited to submit a full proposal. All PPG applications must be submitted electronically via the [proposalCENTRAL website](#) using the provided templates. The research plan section should be typewritten, single-spaced, and in type face no smaller than 10-point font.

Areas of scientific need as outlined in the [Research Emphasis Areas](#) of the JDRF website should be addressed. Applications will be reviewed in open, head-to-head competitions by scientific target area at specified times. Please refer to the [deadlines](#) on the JDRF website for details.

### ***Proposal Title***

The Titles for each individual Project/Core application MUST begin with the last name of the PPG Director (even if some Projects and Cores have different PIs) followed by its component. (e.g. Project 1, 2, 3, etc., Core A, B, C, etc.)

For example, if the PPG Director is John Doe:

PPG Overview Title: "DOE Overview: Mechanisms to develop a cure for Type 1 Diabetes Mellitus"

PPG Project 1 Title: "DOE Project 1: Regulators in Beta Cell Function"

PPG Project 2 Title: "DOE Project 2: Inhibitors of immune deficiency"

PPG Core A Title: "DOE Core A: Mouse Core"

PPG Core B Title: "DOE Core B: Administrative Core"

### ***PPG Proposal***

The Program Project proposal should contain the following: Administrative Information about the Program Project and the Program Project overview.

1. *Administrative Information about the Program Project* - Complete the following forms for the Program Project as a whole:
  - a. Title Page
  - b. Applicant/Program Director
  - c. Institution and Contacts
  - d. Key Personnel
  - e. Abstract
  - g. Organization Assurances
2. *Program Project Overview*: Include a description of the overall goals of the Program Project and each individual project, the relationship of the projects to each other and the Program Project and a composite budget for the entire Program Project. Please see the Overview template for specific information on the page length allowed.

The Project and Core proposals should contain the following: Administrative Information and the Research Plan for the Project or Core:

1. *Individual Projects and Cores*: Each project or core includes a detailed budget, biographical sketches and information about other support for the applicants, and a detailed research plan/core description that should not exceed 10 pages. Tables, charts, figures and references are not counted as part of the page limit.

## **BUDGET**

A budget should be presented for each individual project and core. Funds requested must be used only for expenditures directly related to the research of the grantee. Costs for renovation, alteration or other infrastructure costs are not allowed. Core support may be requested for the normal operating expenses of shared facilities used by most of the investigators in the Program Project. Such expenses include salaries for technicians, equipment, materials and supplies, and maintenance contracts. In addition, requests may be made for the salaries for a limited number of research trainees and other personnel whose participation will enhance the productivity of the Program Project.

Budgets should be quoted in United States dollars and provided for the entire project period. Up to a maximum of USD 660,000 per year total costs for up to three years may be requested.

## **REVIEW CONSIDERATIONS**

Program Project applications will be reviewed according to JDRF's schedule for regular grants and training awards (see grant [deadlines](#) for more information). Applications will be reviewed competitively by a panel of reviewers organized according to the following areas: 1) immunology/ autoimmunity, diabetes prevention and genetics; 2) islet biology and transplantation; and 3) complications.

### ***Scientific Review***

The Program Project application will be assessed in the context of an integrated program, evaluating the team's potential to address issues that could not readily be approached were the components to be funded separately. Each individual project will be evaluated for scientific merit by the scientific review committee and by external reviewers. It is possible that individual projects may not be approved as part of a successful Program Project application.

### ***Lay Review***

There will be Lay Review Committee (LRC) members present at the peer review meeting. Each of the lay reviewers will be assigned applications in a similar manner to the scientific review committee. In addition to having reviewed applications prior to attending the meeting, they will listen to the deliberations and take the reviewers' commentary into consideration as part of the lay review. The LRC meeting will take place following the scientific review. All applications will be examined closely and those deemed inconsistent with the mission of the JDRF will be removed from further consideration. Those applications meeting both the scientific and JDRF criteria will be chosen for the funding recommendations made to the JDRF International Board of Directors.

### ***JDRF Board Review***

The recommendations of the scientific and lay review committees will be presented to the JDRF Board for final approval before funds are awarded.

### ***Review Criteria of Individual Projects***

Each individual project will be evaluated by the review committee and external reviewers. Reviewers will be asked to: 1) assess each project on its own merits; and 2) assess each project as part of the Program Project and whether it should be included in the Program Project. Reviewers will be provided with the full Program Project application to assist them in their evaluation. Each project will be rated from 1.0 to 5.0 in 0.1 increments as indicated in the scoring guide below.

The following questions are among those that will be considered during the review of the individual projects:

- **Significance:** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?
- **Approach:** Are the conceptual framework, design, methods and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?
- **Innovation:** Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?
- **Investigator(s):** Is/are the investigator(s) appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator(s) and other researchers (if any)?
- **Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?
- **Relevance:** How relevant is the work to the goals of the program, i.e. to target research at finding a cure for Type 1 diabetes and its complications that focuses on one of the areas described in the Request for Applications?

### ***Review of the Program Project Aspects***

The relationship and contributions of each individual research project and core to the overall theme of the Program Project application will be evaluated by the review committee and scored using the scoring guide above. Assessment of the overall application is conducted after all individual research projects have been reviewed and rated. Reviews will be performed by an appropriate peer and lay review group. The following criteria are among those which will be considered by the review committee:

- Potential to develop and prove principle of new approaches to unsolved problems of Type 1 diabetes
- Relevance to the objectives of JDRF
- Scientific, technical, or medical significance of the Program Project
- Scientific merit of the Program Project as a whole, as well as that of the individual research projects
- Appropriateness and adequacy of the experimental approach and methodology
- Innovation
- Synergy:
  - Will there be a team of investigators with various types of expertise undertaking collaborative multidisciplinary research in the health sciences in various institutions?
  - Will there be research components, each scientifically meritorious, which together form an integrated research program able to address issues which could not readily be approached were the components to be funded separately?
  - Evaluation of the cohesiveness of the Program Project and the coordination and interrelationships of individual projects and core(s) to the common theme. What are the relative priorities of the various projects, is there a chronological relationship, and should they all be included in the Program Project?
- Investigators:
  - Assessment of the leadership and scientific ability of the principal investigator of the Program Project:

- His or her ability to develop a program of integrated research projects with a well-defined central research focus
- His or her commitment and ability to devote adequate time and effort to the program.
- What is the role of each investigator as part of the Program Project: time commitment and who is going to do what?
- Will each investigator be able to devote adequate time and effort to the program?
- Core facilities: Each core must provide essential facilities or services for two or more individual research projects. Review criteria for scientific cores consist of the following:
  - Justification and usefulness of the core facilities to the various research projects;
  - Relationship of each core to the central focus of the overall Program Project;
  - Quality of relevant facilities or services provided by the core (including procedures, techniques and quality control) and criteria for prioritization and usage;
  - Qualifications, competence and commitment of the Core leader and key personnel.
- Organization and Communication: Will the organizational aspects of the Program Project structure allow the proposed research to occur? Assessment of the plans for meetings, other interactions, and exchange of data, material and techniques. Comment on the geographical distribution of the Program Project members.
- Institutional and other sources of support: What is the institutional commitment to the Program Project and the impact of the Program Project on the institutions involved in terms of research priorities of the institution, financial support, time protection, and laboratory space and equipment? Are there any other sources of financial support for the request, which could include: cost-sharing arrangements with the sponsoring institution(s), industry (keeping in mind that university-industry collaborations are encouraged), or other agencies; estimates of institutional expenditures involved in upgrading or constructing laboratory facilities; estimates of indirect institutional support such as provision of services and computing resources; user fees.

## **TERMS OF THE AWARD**

JDRF Program Projects will be supported for a maximum of USD 660,000 total costs per year for a period of up to 3 years. Program Projects can consist of 3 to 6 individual projects and 1 to 3 core services. Indirect costs cannot exceed 10% of direct costs minus equipment costs and/or subcontract costs if indirect costs are included in the budget submitted by the subcontracting organization. Evidence of institutional commitment in the form of dollars or resources is also highly desirable. Support beyond 3 years will be determined based on a competitive review of the accomplishments and future plans of the Program Project.

An annual progress report will be due 2 months prior to the anniversary date of the award, except in the final year, in which the progress report is due 2 months following the close of the award. In some instances, JDRF may also elect to evaluate the Program Project through a site visit or reverse site visit.

## CLINICAL INVESTIGATIONS RESEARCH GRANT

**Note:** Only applicants who have an approved JDRF Letter of Intent (LOI) for a Clinical Investigations Research Grant may submit applications under this category. If you submit a Clinical Grant application without a prior LOI approval, your application will not be considered.

### DESCRIPTION

JDRF Clinical Investigations Research Grants are intended to support clinical research programs that exceed the fiscal limitation of the JDRF regular grant mechanism and/or do not fit the structure of the Center or Program Project Grant mechanisms. JDRF places special value in translational research proposals that lead to and develop unique and innovative solutions to the clinical problems of people with diabetes. This funding mechanism is intended to support early-stage clinical trials to test novel therapeutic approaches as well as non-interventional patient oriented studies that are intended to lead to the development of clinical interventions and monitoring tools (such as surrogate markers) for diabetes and its complications. Applications for Clinical Investigations Research Grants must be goal oriented and closely focused on the JDRF mission.

### ELIGIBILITY

Applicants must hold an MD, DMD, DVM, PhD, or equivalent and have a faculty position or equivalent at a college, university, medical school, company, or other research facility. Applications may be submitted by domestic and foreign non-profit organizations, public and private, such as colleges, universities, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government that are accredited to perform clinical research.

Ordinarily, for-profit organizations will not be considered, except under special circumstances. See the [Industry Discovery & Development Partnerships section](#) for a description of special program for for-profit entities.

There are no citizenship requirements for this program. To assure continued excellence and diversity among applicants and awardees, JDRF welcomes applications from all qualified individuals and encourages applications from persons with disabilities, women, and members of minority groups underrepresented in the sciences.

**Note:** For additional information on application guidelines for clinical studies, click [here](#).

### LETTER OF INTENT

Prospective applicants should submit a letter of intent on-line via the [proposalCENTRAL website](#). The LOI template provided on the proposalCENTRAL website must be used to complete the application. The LOI should address clinical study design, plans for patient recruitment and informed consent, the potential benefits and information about the risks to patients, plans to minimize potential risks, and the likely effectiveness of such plans. For proposed clinical trials, the letter should also include a power calculation and a data safety monitoring plan. Research project descriptions should contain sufficient detail to allow JDRF to identify potential scientific reviewers to review the application.

Applicants will be notified four (4) weeks after the LOI deadline date if they have been approved to continue forward to submit a full application.

### APPLICATION

If the applicant's LOI has been approved by JDRF, the applicant will be invited to submit a full proposal. All Clinical Investigations Research Grant Applications must be submitted electronically via

the [proposalCENTRAL website](#) using the provided JDRF Proposal Narrative Template. The narrative section should be typewritten, single-spaced, and in type face no smaller than 10-point font.

Proper assurances on the safety of human subjects must be addressed in the Human Subjects Research Plan, generally not to exceed 3 pages. The Human Subjects Research Plan must address all items outlined in section B of the [JDRF Guidelines for Clinical Investigations Research Proposals](#).

*Provision of copies of draft or final Institutional Review Board (IRB) application materials and subject information and consent form(s) (if available) is strongly recommended. If the application is approved for funding, no funds will be released until 1) IRB approval for the study is received and 2) The final IRB-approved consent form is received.*

## **RESEARCH PLAN AND BUDGET**

The Research Plan for a Clinical Investigation should not exceed 10 pages. Tables, charts, figures, references, and the Human Subjects Research Plan are not counted as part of the Research Plan page limits. The Research Plan must be organized as follows: a) Specific Aims; b) Background and Significance of this work to Type 1 Diabetes; c) Preliminary Studies/Progress Report (for competitive renewal); d) Research Design and Methods; e) Literature Cited (no page limit); f) Principle Investigator Assurance. *All information in items a through d must be incorporated in the 10-page limit without exception.*

A budget should also be presented. Funds requested must be used only for expenditures directly related to the research of the grantee. Core support may be requested for the normal operating expenses of shared facilities used by the clinical study. Such expenses include salaries for technicians, equipment, materials and supplies, and maintenance contracts. Budgets should be quoted in United States dollars and provided for the entire project period. (Up to a maximum of USD 660,000 per year total costs for a period of 3 to 5 years may be requested.)

## **RESEARCH PROPOSAL GUIDELINES**

JDRF supports clinical investigative research that seeks to translate basic research discoveries to cure, prevent and/or reverse Type 1 diabetes and its complications. The JDRF Clinical Investigations Study Section will review applications that propose, as a central focus, a clinical trial or other “hands on” patient clinical investigative study. Applicants should follow the [general guidelines for research proposals](#) and should also include information about the clinical study design and ethical requirements regarding human research subject participation.

## **REVIEW CONSIDERATIONS**

### ***Scientific Review***

Clinical Investigation Grant proposals will be evaluated by a Clinical Investigations Study Section composed of experts in trial design, biostatistics, clinical trials management, and ethics and behavioral issues, as well as by relevant scientific experts. The review criteria will include:

- Potential to prove principle of new approaches to unsolved problems of type 1 diabetes;
- Relevance to the objectives of JDRF;
- Scientific, technical, or medical significance of the research proposal;
- Innovative quality of the proposed study;
- Soundness of the clinical study design;
- Availability of sufficient pre-clinical data to justify the proposed clinical study;
- Qualifications and research experience of the principal investigators and collaborators;
- Consideration of the potential benefits and risks to patients who will be involved in the research, plans to limit risks, and other ethical considerations;

- Availability of resources and facilities necessary for the study;
- Appropriateness of the proposed budget in relation to the proposed research.

### ***Lay Review***

There will be Lay Review Committee (LRC) members present at the peer review meeting. Each of the lay reviewers will be assigned applications in a similar manner to the scientific review committee. In addition to having reviewed applications prior to attending the meeting, they will listen to the deliberations and take the reviewers' commentary into consideration as part of the lay review. The LRC meeting will take place following the scientific review. All applications will be examined closely and those deemed inconsistent with the mission of the JDRF will be removed from further consideration. Those applications meeting both the scientific and JDRF criteria will be chosen for the funding recommendations made to the JDRF International Board of Directors.

### ***JDRF Board Review***

The recommendations of the scientific and lay review committees will be presented to the JDRF Board for final approval before funds are awarded.

### **TERMS OF THE AWARD**

JDRF Clinical Investigations Research Grants will be supported for a maximum of USD 660,000 total costs per year for a period of up to 5 years. Indirect costs cannot exceed 10 percent of direct costs and institutional support is encouraged but not required.

An annual progress report will be due 2 months prior to the anniversary date of the award, except in the final year, in which the progress report is due 2 months following the close of the award.

### **CONTACT**

Inquiries regarding LOIs and intended applications proposing clinical investigations should be directed to [JDRF Science Staff](#):

## CENTER GRANTS – No Center Grants RFA for FY 2009

### DESCRIPTION

JDRF Centers for Diabetes Research are intended to provide leading scientists and clinicians with the opportunity to bring together, in a collaborative and mission-driven environment, the diverse expertise needed to capture and rapidly translate new and emerging ideas into clinical benefits for people with diabetes. In general, the major focus of a JDRF Center should be in one of the following target areas:

- Human Islet Transplantation
- Complications, including hypoglycemia
- Autoimmunity and Prevention

It is recognized that Centers may have individual projects that overlap these target areas. JDRF Research Centers should be organized to support collaboration between scientific disciplines and between bench scientists and clinical researchers. A Center must have a clear clinical mission with defined goals and milestones and all efforts coordinated through strong scientific and administrative leadership. Projects incorporated into the Center should demonstrate a focus on reaching scientifically relevant milestones ultimately aimed at a specific clinical outcome. Centers should be dynamic entities where new projects may be initiated and other projects terminated as dictated by scientific progress. As a resource for type 1 diabetes research, centers will be expected to attract additional funding from other appropriate sources, such as the investigators' institution or the NIH to enhance the mission. The Center director will be expected to provide strong intellectual and scientific leadership and milestone based management of the Center's component projects. For the typical Center, a portion of funds, up to 5 percent of the Center budget, may also be dedicated to support pilot and feasibility projects or to use at the director's discretion.

Senior scientists and clinicians working in institutions with endowed or strong NIH, other third-party, or other JDRF funded research programs may wish to present proposals for JDRF Center funding which emphasize use of new JDRF funds as the "catalyst" to bring together independently funded projects around a common diabetes-related clinical mission. As such, these funds could be used to establish an administrative core; to establish an informatics infrastructure to enhance information sharing; to promote formal (and informal) collaborative interaction; to fund critical core resources; to seed pilot and feasibility work; or to supplement key research projects. In this model, the intent is for JDRF funds to link otherwise separate scientific resources already present and funded at an institution in a way that allows these resources to collaborate in new and innovative ways. These JDRF "catalyst" Center proposals will have to compete with more typical Center proposals and therefore will need to present a compelling case for how on-going research funded independently of the center (including independently funded by NIH, JDRF, etc), will be integrated to serve the Center's mission, how new independently funded work and other resources will be recruited to participate in the Center, and how such a grant uniquely will allow collaboration among researchers.

**Note:** Applications proposing research with human subjects must be submitted to the Clinical Investigations Study Section, with the exception of studies using only human tissue (i.e. cell lines, blood, urine, etc.) without **ongoing** patient contact.

All applications to the Clinical Investigations Study Section, regardless of grant mechanism, must follow the [Guidelines for Clinical Investigations Research](#) and must include a Human Research Subject Plan. Clinical applications without such a plan will be administratively triaged.

All applicants proposing human embryonic stem cell research must read the [JDRF Policy Statement/Guidelines for the use of Human Embryos in Stem Cell Research](#). Applicants proposing the use of human fetal tissue must read the [JDRF Policy Statement/Guidelines for the use of Human Fetal Tissue in Research](#).

**Table 3: Key Elements Distinguishing JDRF Centers and Program Projects**

Element	Center	Program Project
<b>Director</b>	<ul style="list-style-type: none"> <li>• Established diabetes investigator</li> <li>• Milestone-based management</li> <li>• Can add or delete projects</li> <li>• Re-budgeting authority</li> </ul>	Milestone-based management
<b>Goals</b>	Long Term	2 to 3 years
<b>Approaches</b>	Diverse	Interactive
<b>Projects</b>	<ul style="list-style-type: none"> <li>• No upper limit</li> <li>• Enter and leave</li> <li>• “Catalyst” Alternative</li> </ul>	<ul style="list-style-type: none"> <li>• 3 to 6</li> <li>• Define program</li> </ul>
<b>Administrative Core</b>	Yes	When justified
<b>Clinical Outcome</b>	Yes	Not required
<b>External Scientific Advisory Board</b>	Yes	No
<b>On-site/reverse-site visits</b>	Yes	As required
<b>Pilot and feasibility project funding</b>	Yes	No

## ELIGIBILITY

Applicants must hold an MD, DMD, DVM, PhD, or equivalent and have a faculty position or equivalent at a college, university, medical school, company, or other research facility. Applications may be submitted by domestic and foreign non-profit organizations, public and private, such as colleges, universities, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government. Applications may be submitted by domestic and foreign non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government. Ordinarily, for-profit organizations will not be considered, except under special circumstances (see the [Industry Discovery & Development Partnerships section](#) for a description of special program for for-profit entities).

There are no citizenship requirements for this program. To assure continued excellence and diversity among applicants and awardees, JDRF welcomes applications from all qualified individuals and encourages applications from persons with disabilities, women, and members of minority groups underrepresented in the sciences.

## LETTER OF INTENT

A letter of intent (LOI) is required. Centers will be evaluated on a competitive basis and LOIs will be grouped by scientific target areas for review. Dates for submission of letters of intent in specific target areas will be announced by JDRF on a regular basis. Review groups will focus on applications in the following target areas:

- Human Islet Transplantation
- Complications
- Autoimmunity and Prevention

Prospective applicants should submit a letter of intent that includes a descriptive title of the proposed Center and a clear mission statement. Also included should be the name, address, telephone number, and email address of the Center Director, estimated budget, the identities of other key personnel and participating institutions, and the titles and a short description of component projects and cores. Research project descriptions should contain sufficient detail to allow JDRF to identify potential scientific reviewers to review the application. "Catalyst" Center LOI's must describe the third-party funded science that will be integrated into the Center. The letter should also indicate the review group to which the application should be assigned and should not exceed 10 pages. The signed Letter of Intent should be submitted via [proposalCENTRAL](#).

## APPLICATION

**Note:** Upon approval of the LOI, only the Center Overview application will become automatically available. The Principal Investigators of individual Projects & Cores, must complete separate online applications on the [proposalCENTRAL website](#) for each Center Project/Center Core.

If the applicant's LOI has been approved by JDRF, the applicant will be invited to submit a full proposal. All Center Grant Applications must be submitted electronically via the [proposalCENTRAL website](#) using the provided JDRF Proposal Narrative Template. The narrative section should be typewritten, single-spaced, and in type face no smaller than 10-point font.

Areas of scientific need as outlined in the [Research Emphasis Areas](#) of the JDRF website should be addressed. Applications will be reviewed in open, head-to-head competitions by scientific target area at specified times. Please refer to the [deadlines](#) on the JDRF website for details.

### ***Proposal Title***

The Titles for each individual Project/Core application MUST begin with the last name of the Center Director (even if some Projects and Cores have different PIs) followed by its component. (e.g. Project 1, 2, 3, etc., Core A, B, C, etc.)

For example, if the Center Director is John Doe:

Center Overview Title: "DOE Overview: Mechanisms to develop a cure for Type 1 Diabetes Mellitus"

Center Project 1 Title: "DOE Project 1: Regulators in Beta Cell Function"

Center Project 2 Title: "DOE Project 2: Inhibitors of immune deficiency"

Center Core A Title: "DOE Core A: Mouse Core"

Center Core B Title: "DOE Core B: Administrative Core"

### ***Center Proposal***

The Center Overview — includes a description of the overall goals of the Center and each individual project, the relationship of the projects to each other and the Center and a composite budget for the entire Center.

The Center proposal should contain the following: Administrative Information about the Center and the Center overview.

1. Administrative Information about the Center — Complete the following forms for the Center as a whole:
  - a. Title Page
  - b. Applicant/Center Director
  - c. Institution and Contacts
  - d. Key Personnel
  - e. Abstract
  - g. Organization Assurances
2. Center Overview — includes a description of the overall goals of the Center and each individual project, the relationship of the projects to each other and the Center and a composite budget for the entire Center. Please see the Overview template for specific information on the page length allowed.

The Project and Core proposals should contain the following: Administrative Information and the Research Plan for the Project or Core:

1. Individual Projects and Cores — each project or core includes a detailed budget, biographical sketches and information about other support for the applicants, and a detailed research plan/core description that should not exceed 10 pages. Tables, charts, figures and references are not counted as part of the page limits.

### **Budget**

A budget should be presented for each individual project and Core. Funds requested must be used only for expenditures directly related to the research of the grantee. Costs for renovation, alteration or other infrastructure costs are not allowed. Core support may be requested for the normal operating expenses of shared facilities used by multiple investigators in the Center. Such expenses include salaries for technicians, equipment, materials and supplies, and maintenance contracts. In addition, salaries for a limited number of research trainees and other personnel whose participation will enhance the productivity of the Center may be requested.

Budgets should be quoted in United States dollars and provided for the entire project period. Up to a maximum of USD 2 million per year total costs for up to five years may be requested. Because clinical trials are a major activity of JDRF Centers, proper assurances on the safety of human subjects must be demonstrated. The applicant must provide a copy of the Institutional Review Board (IRB) approved consent form, or nearly finalized draft, with the application. Plans for the formation of a Data Safety Monitoring Board (DSMB) should also be presented. Finally, the dynamic and collaborative nature of a JDRF Center requires careful guidance and attention beyond the responsibilities of the Center Director or a single individual, and as such, an external scientific advisory board should be formed and plans for its function within the Center should be presented in the application.

If the application is approved for funding, no funds will be released until: 1) IRB approval for the study is received and 2) Final IRB-approved consent form is received.

### **REVIEW CONSIDERATIONS**

Applications will be grouped by topic and will be evaluated on a regular basis in accordance with the criteria described below. Evaluations will be competitive and performed by an appropriate peer and lay review group convened by the JDRF (see the [Review section](#), above, for more information).

Application deadlines and review dates will be communicated to the Center Director after review and approval of the LOI.

The JDRF Center review criteria will include:

- Clarity of stated mission and goals and research plan;
- Qualifications and research experience of the Center Director, investigators, and collaborators;
- Strength of scientific and administrative leadership as well as demonstration of institutional support;
- Potential to develop and prove principle of new approaches to unsolved problems of type 1 diabetes;
- Quality of informatics support, and clearly demonstrated opportunities for structured and unstructured information sharing;
- Demonstration of core resources that could expand to support non-JDRF funded projects and willingness to recruit third party funded researchers to participate in contributing to achieving the Center mission;
- Relevance to the research objectives of JDRF;
- Scientific, technical, or medical significance of the Center's projects;
- Innovation;
- Appropriateness and adequacy of the experimental approach and methodology;
- JDRF Centers are expected to have a clinical research component or show progress from basic research toward clinical application in years 1 through 5;
- Availability of resources and facilities necessary to function as a Research Center;
- Synergy of individual components to achieve the goals of the Center;
- Appropriateness of the proposed budget and duration in relation to the proposed research;
- For proposed clinical studies within the Center, review criteria will include soundness of the clinical study design, consideration of the potential benefits and risks to patients who will be involved in the research, plans to limit risks, and other ethical considerations.

### ***Scientific Review***

The Center application will be assessed in the context of an integrated program, evaluating the team's potential to address issues that could not readily be approached were the components to be funded separately. Each individual project will be evaluated for scientific merit by an external scientific review committee. It is possible that individual projects may not be approved as part of a successful Center application.

### ***Lay Review***

There will be Lay Review Committee (LRC) members present at the review. Each of the lay reviewers will be assigned applications in a similar manner to the scientific review committee. In addition to having reviewed applications prior to attending the meeting, they will listen to the deliberations and take the reviewers' commentary into consideration as part of the lay review. The LRC meeting will take place following the scientific review. All applications will be examined closely and those deemed inconsistent with the mission of JDRF will be removed from further consideration. The applications will be reviewed in a manner similar to the scientific review and those applications meeting both the scientific and JDRF criteria will be chosen for the funding recommendations made to the JDRF International Board of Directors.

### ***JDRF Board Review***

The recommendations of the scientific and lay review committees will be presented to the JDRF Board for final approval before funds are awarded.

### ***Review Criteria of Individual Projects***

Each individual project will be evaluated by the review committee. Reviewers will be asked to: 1) assess each project on its own merits; and 2) assess each project as part of the Center and whether it should be included in the Center. Reviewers will be provided with the full Center application to assist them in their evaluation. Each project will be rated from 1.0 to 5.0 in 0.1 increments as indicated in the scoring guide below.

The following questions are among those that will be considered during the review of the individual projects:

- Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?
- Approach: Are the conceptual framework, design, methods and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?
- Innovation: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?
- Investigator(s): Is/are the investigator(s) appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator(s) and other researchers (if any)?
- Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?
- Relevance: How relevant is the work to the goals of the program, i.e. to target research at finding a cure for Type 1 diabetes and its complications that focuses on one of the areas described in the Request for Applications?

### ***Review of Center Project Aspects***

The relationship and contributions of each individual research project and core to the overall theme of the Center application will be evaluated by the review committee and scored using the JDRF scoring guide. Assessment of the overall application is conducted after all individual research projects have been reviewed and rated. Reviews will be performed by an appropriate peer and lay review group.

The following criteria are among those which will be considered by the review committee:

- Clarity of stated mission and goals and research plan
- Scientific, technical, or medical significance of the Center's projects
- Relevance: how relevant is the research proposed to the goals of the program (i.e., to target research at finding a cure for Type 1 diabetes and its complications that focuses on one of the areas described in the Request for Applications)?
- Potential to develop and prove principle of new approaches to unsolved problems of Type 1 diabetes
- Scientific merit of the Center as a whole, as well as that of the individual research projects
- Appropriateness and adequacy of the experimental approach and methodology
- Investigators:
  - Assessment of the leadership and scientific ability of the Director of the Center:
    - his or her ability to develop a program of integrated research projects with a well-defined central research focus;

- his/her commitment and ability to devote adequate time and effort to the program.
  - What is the role of each investigator as part of the Center: time commitment and who is going to do what? Will each investigator be able to devote adequate time and effort to the program?
- JDRF Centers are expected to have a clinical research component or show progress from basic research toward clinical application in years 1 through 5.
- For proposed clinical studies within the Center, review criteria will include soundness of the clinical study design, consideration of the potential benefits and risks to patients who will be involved in the research, plans to limit risks, and other ethical considerations.
- Innovation
- Synergy
  - Will there be a team of investigators with various types of expertise undertaking collaborative multidisciplinary research in the health sciences in various institutions?
  - Will there be research components, each scientifically meritorious, which together form an integrated research program able to address issues which could not readily be approached were the components to be funded separately?
  - Evaluation of the cohesiveness of the Center and the coordination and interrelationships of individual projects and core(s) to the common theme. What are the relative priorities of the various project, is there a chronological relationship, and should they all be included in the Center?
- Appropriateness of the proposed budget and duration in relation to the proposed research.
- Availability of resources and facilities necessary to function as a Research Center.
- Core facilities: each core must provide essential facilities or services for two or more individual research projects. Review criteria for scientific cores consist of the following:
  - Justification and usefulness of the core facilities to the various research projects;
  - Relationship of each core to the central focus of the overall Center;
  - Quality of relevant facilities or services provided by the core (including procedures, techniques and quality control) and criteria for prioritization and usage;
  - Qualifications, competence and commitment of the Core leader and key personnel;
  - Demonstration of core resources that could expand to support non-JDRF funded projects and willingness to recruit third party funded researchers to participate in contributing to achieving the Center mission
- Quality of Informatics support, and clearly demonstrated opportunities for structured and unstructured information sharing
- Organization and Communication: will the organizational aspects of the Center structure allow the proposed research to occur? Assessment of the plans for meetings, other interactions, and exchange of data, material and techniques. Comment on the geographical distribution of the Center members, keeping in mind that the inclusion of researchers from different Centers is encouraged.
- Training: will the research setting permit research training?
- Institutional and other sources of support: what is the institutional commitment to the Center and the impact of the Center on the institutions involved in terms of research priorities of the institution, financial support, time protection, and laboratory space and equipment? Are there any other sources of financial support for the request, which could include: cost-sharing arrangements with the sponsoring institution(s), industry (keeping in mind that university-industry collaborations were encouraged), or other agencies; estimates of institutional expenditures involved in upgrading or constructing laboratory facilities; estimates of indirect institutional support such as provision of services and computing resources; user fees.


## **TERMS OF AWARD & EVALUATION**

JDRF centers for Diabetes Research will be supported for a maximum of USD 1.5 million total costs per year for a period of up to 5 years. Indirect costs cannot exceed 10% of direct costs minus equipment costs and/or subcontract costs if indirect costs are included in the budget submitted by the subcontracting organization. Evidence of institutional commitment in the form of dollars or resources is also highly desirable. Support beyond 5 years will be determined based on a competitive review of the accomplishments and future plans of the center.

A detailed process for the evaluation of progress will be determined at time of award. At a minimum, it will require an annual written progress report, due two months prior to the anniversary date of the award. Evaluations may occur in the form of on-site or reverse-site visits by an outside panel of experts, working with JDRF volunteer leaders. Visits will be coordinated together with JDRF staff. Based on the results of the progress report, funding may be revised as determined by the JDRF.

## INDUSTRY DISCOVERY & DEVELOPMENT PARTNERSHIPS

**Note:** Companies interested in applying for JDRF Industry Discovery & Development Partnerships (IDDP) are encouraged to first contact Paul Burn, Ph.D., Senior Vice President of Research and Development:

 212-479-7572

 [pburn@jdrf.org](mailto:pburn@jdrf.org)

### PURPOSE

The IDDP Program aims to promote for-profit interest in JDRF's mission. Specifically, we seek meaningful relationships with biotech and pharmaceutical partners focused on the discovery, development and commercialization of therapeutics for type 1 diabetes (T1D) and its complications. JDRF Industry funding can support research programs in companies or for-profit entities, publicly or privately held, focused on one of the following JDRF mission areas:

#### Restore Beta Cell Function

- Regenerate the body's own beta cells
- Replace beta cells by transplantation with a "universal donor" source of insulin-secreting cells without the use of chronic immunosuppression

#### Restore Immunoregulation

- Reverse or prevent T1D by maintaining or restoring immune tolerance or immunoregulations

#### Prevent, Postpone, Reverse Diabetic Complications


JDRF particularly encourages proposals to develop or test, in preclinical models or early-stage clinical trials, novel therapeutic approaches for diagnosis, prevention or treatment of T1D or its complications. It is intended that the IDDP Program will present an opportunity for JDRF to foster long-term collaborative relationships with industry taking promising research through discovery and development and toward commercialization. JDRF encourages companies proposing collaboration with academic researchers.

### STRUCTURE

JDRF is prepared to fund applied research programs at different stages of development up to USD 5 million per program. It is expected that collaborating companies must demonstrate a matching resource commitment to the proposed program that is equal to or greater than that requested from JDRF. JDRF funded companies will be expected to enter into a research agreement with JDRF regarding milestones to be met in relation to anticipated funding, intellectual property and JDRF participation. These will be negotiated on a case-by-case basis.

### APPLICATION

JDRF encourages interested companies to initially contact Dr. Paul Burn, Senior Vice President of Research and Development:

 212-479-7572

 [pburn@jdrf.org](mailto:pburn@jdrf.org)

Formal IDDP applications must be preceded by a letter of intent (LOI). Both LOI's and applications will be reviewed on a rolling basis.

## SCHOLAR AWARD

### DESCRIPTION

In an effort to expedite the progress toward a cure for type 1 diabetes, the Juvenile Diabetes Research Foundation (JDRF) offers a Scholar Award. This award offers sustained support for pioneering basic or clinical research aimed at fulfilling the goals of JDRF—finding a cure for type 1 diabetes or its complications. The Scholar Award is designed to support individual scientists of exceptional creativity who propose pioneering research to reach these goals. The Scholar Award will fund investigators with extraordinary talent and vision, who are willing to take risks and attempt new approaches to accelerate type 1 diabetes research. The Scholar Award is meant to support investigators who intend to pursue new research directions that are not funded from other sources. The awards are not intended simply to expand the funding of persons already well supported for exploring this concept.

### ELIGIBILITY

Applications may be submitted by researchers who hold an academic degree (DMD, DO, DVM, MD, PhD, or equivalent) in a scientific discipline and who also hold an independent investigator position at a university, health-science center, or comparable institution. The candidate will typically have at least seven years of relevant experience since receiving his/her degree. Scholar Award research may be conducted in any nation, within for-profit or non-profit, public or private organizations, such as universities, colleges, hospitals, laboratories, units of state and local governments, or eligible agencies of federal governments.

There are no citizenship requirements for this program. To assure continued excellence and diversity among applicants and awardees, JDRF welcomes applications from all qualified individuals and encourages applications from persons with disabilities, women, and members of minority groups underrepresented in the sciences.

### TERMS OF THE AWARD

The Scholar Awards will each provide up to USD 250,000 annually, including indirect costs, for up to five years.

### APPLICATION

All applications must be completed using the templates provided on the [proposalCENTRAL website](#). **Please continue to check our [Application Deadlines](#) document on the JDRF website for more information about upcoming Scholar deadlines.**

## **HIGH PRIORITY, SHORT-TERM BRIDGE AWARD**

### **DESCRIPTION**

JDRF recognizes the need at this time to support the research of investigators whose research is being curtailed or delayed by failure to receive funding. It is beneficial and of mutual interest to both the scientific community and JDRF to keep these scientists in the field, to help them receive funding for their proposals, and to have them help accelerate the JDRF mission. This award will provide one year of funding for research grant applications that address a high priority research area for JDRF and scored within 10% of the funding payline for a review cycle of a research funding agency up to a year prior to the request to JDRF. The goal of this “bridge” funding is to help investigators generate additional supporting data for an amended, competitive application.

### **ELIGIBILITY**

Applications may be submitted by domestic and foreign non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government. Applications must hold an MD, DMD, DVM, PhD, or equivalent and have a faculty position or equivalent at a college, university, medical school, or other research facility. There are no citizenship requirements for this program.

To assure continued excellence and diversity among applicants and awardees, JDRF welcomes applications from all qualified individuals and encourages applications from persons with disabilities, women, and members of minority groups underrepresented in the sciences.

### **TERMS OF THE AWARD**

The High Priority, Short-Term Bridge Awards will each provide up to USD 55,000 annually, including indirect costs, for up to one year.

### **APPLICATION**

All applications must be completed using the templates provided on the [proposalCENTRAL website](#). Click here for more information on specific [template/proposal requirements](#).

## **ACADEMIC RESEARCH & DEVELOPMENT AWARD**

### **DESCRIPTION**

Academic Research & Development (R&D) grants are JDRF-initiated research or development projects that are identified by JDRF staff and developed into grant proposals in collaboration between JDRF staff and academic investigators. Proposals are evaluated by scientific peer reviewers and are recommended for funding by JDRF staff, lay reviewers and the Research Development Committee (RDC) to the JDRF Board or Executive Committee for approval.

### **ELIGIBILITY**

The Program Directors are responsible for proactively identifying opportunities in the academic setting that enhance and fit the strategic objectives of their respective program areas and that allow them to deliver on their mission to bring products to the patient in a timely manner. In addition, anybody (including staff, lay reviewers, board members, academic investigators etc.) can identify potential opportunities and bring them to the attention of the appropriate Program Director.

Staff will actively engage with the potential academic partner to develop a full application that satisfies the needs of JDRF. The Program Director leads the discussions and is responsible for the scientific aspects of the application, including milestones, deliverables and budget. External scientific peer review will be solicited by the Program Director. Proposals that involve clinical trials will also have specialized ethical and clinical trial reviews.

Applications must hold an MD, DMD, DVM, PhD, or equivalent and have a faculty position or equivalent at a college, university, medical school, or other research facility. There are no citizenship requirements for this program.

### **TERMS OF THE AWARD**

Available funding for the Academic R&D Award will be reviewed on a per-application basis. Decisions on continued funding are made by the Program Director in consultation with Senior Management based on progress on milestones.

### **APPLICATION**

All applications must be completed using the templates provided on the [proposalCENTRAL website](#). Click here for more information on specific [template/proposal requirements](#).

## SECTION 3: SCIENTIFIC GUIDELINES

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### INTRODUCTION

All applications—regardless of award mechanism—related to (1) clinical research involving ongoing patient contact, (2) islet transplantation in humans, or (3) use of human embryos or fetal tissue must conform to JDRF guidelines and policies, listed below. Applications that are not consistent with these guidelines will be administratively triaged without review.

### CLINICAL INVESTIGATIONS GUIDELINES

JDRF supports clinical investigative research that seeks to translate basic research discoveries to cure, prevent and/or reverse Type 1 diabetes and its complications. The JDRF Clinical Investigations Study Section will review applications that propose, as a central focus, a clinical trial or other “hands on” patient clinical investigative study. Applicants should follow general guidelines for research proposals and also include information about the clinical study design and ethical requirements regarding human research subject participation.

#### *Clinical Study Design*

All applications that propose clinical investigation studies must include within the proposal Research Plan information about the clinical study design and analysis. The following components of study design analysis should be specifically addressed in each proposal:

1. Summary of proposed study objectives and design: Briefly state the goal of the study, describe the study design, and justify its use. If alternative study designs are possible (for example, randomized placebo control, cross-over, open label, etc.), discuss the reasons for choosing the proposed design. Identify the planned outcome measures and surrogate markers.
2. Subject recruitment and enrollment: Explicitly state inclusion and exclusion criteria for persons with Type 1 diabetes, at risk for Type 1 diabetes, family members, and healthy control subjects. Justify why these are chosen and discuss effect on potential recruitment where appropriate. Briefly describe plans for the type (health and disease status) and numbers of patients and controls to be enrolled, planned randomization procedures, and plans for how and over what duration study subjects will be recruited.
3. Study evaluation and statistical analysis: Include a brief non-technical description of how study results will be evaluated to support or provide evidence against the study hypothesis, including statistical methods to be employed. Include a rationale for proposed sample sizes. (This will generally rely on the typical distribution of the primary outcome measure in the target population and on anticipated effects in the study.) For clinical trials, include a power calculation. If applicable, provide alternative sample size and study design if a Bayesian analysis approach was adopted.

#### *Human Research Subject Plan*

All applications that propose clinical investigation studies must include a Human Research Subject Plan, which should be submitted separately from the general research plan. The Human Subjects Research Plan should address the items below and generally should not exceed three pages.

##### 1. Criteria for subject inclusion/exclusion:

Describe the proposed involvement of human research subjects, including patients and healthy control subjects, stating their anticipated number, age range, sex, ethnic/racial background, and health status. Identify the criteria for inclusion or exclusion of any subpopulation, including children

and adolescents. Include consideration of the privacy rights of both former and current patients. For example, address how previous guarantees of confidentiality in clinical or research settings will be honored in the way potential subjects are contacted.

## 2. Potential benefits and risks to subjects, plans to minimize risks and knowledge to be gained from the study:

In narrative format, for each proposed intervention and for each proposed subject group address the following factors<sup>1</sup>:

- Describe potential direct and indirect benefits to the individual subject and/or group of subjects
- Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects, including potential risks to healthy control subjects.
- Note potential risks to pregnant women and fetuses.

<sup>1</sup> Applicants may supplement the narrative with a tabular presentation of benefits, risks, and plans to minimize risks for each intervention and each subject group. See Appendix A.

For research involving children and adolescents, classify the risk level for each intervention and each subject group, according to the categories in the U.S. Department of Health and Human Subjects Federal Regulations 45CFR46 Subpart D (see Appendix B).

- Describe the planned procedures for protecting against or minimizing potential risks and assess their likely effectiveness.
- Discuss the importance of the potential benefit to society through knowledge to be gained as a result of the proposed research. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

## 3. Monitoring study subject safety:

Discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects for the subjects. For proposed clinical trials (biomedical and behavioral intervention studies) include a data safety-monitoring plan. The plan should identify a responsible entity to perform the monitoring and the planned procedures for reporting adverse events. The elements of the plan may vary depending on the clinical study design and potential risks.

## 4. Sources of research material and confidentiality protections:

Identify sources of research materials obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether these materials or information will be obtained specifically for research and how these materials or information will be used.

Address planned measures to protect the confidentiality of study subjects and subject materials and information generated by the study.

## 5. Costs, incentives, and remuneration:

Describe any potential costs for study subjects. Describe any incentives or remuneration that research subjects will receive by study participation or compensation for injury incurred as a result of study participation. For research studies that propose remuneration for participation of minor subjects, state whether the remuneration is offered to parents or their minor children.

## 6. Research subject informed consent:

Consent plans: Describe plans for the process for obtaining subject informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it,

the nature of the information to be provided to prospective subjects, and the method of documenting consent. Recognize that consent is an interactive process and that a signed form is merely evidence that the interaction took place.

*Assent of minors:* For research studies involving children or adolescents, discuss plans for obtaining assent of those minors capable of doing so.

When available, submission of a draft or IRB-approved patient information and consent (assent) documents is strongly recommended.

*Guidelines for the informed consent document are provided in Appendix C.*

Submission of the finalized patient information and consent forms and written IRB approval will be required prior to initiation of funding.

#### 7. Conflict of interest:

State whether study personnel responsible for the design, conduct, or reporting of the research has an economic interest in, or acts as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by, the research.

#### 8. Investigator education in the protection of human research subjects:

Describe, for all key personnel, education on the protection of human research subjects.

#### 9. Projects involving drugs or devices

State whether the proposed clinical investigation involves the use of any drugs or devices and whether the drug or device is approved for the intended application. If not approved for the intended application, please indicate:

IND# or IDE#

Phase of the clinical study

Who holds the IND for this drug?

#### Submission of the FDA-IND letter, where applicable, will be required prior to initiation of funding.

Prior to funding, the following information will be required:

- Documentation of IRB review and approval (or international local ethics board equivalent)
- Sample human subject (patient) information and informed consent documents
- Documentation for human research subject education of key study personnel
- For clinical trials, a data safety monitoring plan
- Institutional assurance that the research is in accord with relevant national, state local and international law
- Copy of the FDA-IND letter, where applicable JDRF will require annual review of funded clinical investigation research. Continued funding will be contingent on the researchers' ability to enroll patients and to ensure patient safety.

**APPENDIX A - Tabular presentation of risks and benefits per intervention per research study group (optional format to accompany required narrative description for Section B-2)**

<b>Intervention</b>	<b>Research Subject Group</b>	<b>Risk</b>	<b>Benefit</b>
Aim 1 - Blood draw	Newly diagnosed T1D patients, age 18 or older	Minimal	None
	Normal healthy subjects, age 18 or older	Minimal	None
Aim 2 - Administration of test drug	Newly diagnosed T1D patients, treatment group	Short-term risk of mild side effects (fever, rash)	May get positive effect of drug
	Newly diagnosed T1D patients, placebo control group	Minimal	None

**APPENDIX B - U.S. Department of Health and Human Services Regulations Title 45 Part 46 Subpart D requirements for the participation of children in research**

Subpart D of the human subjects regulations establishes requirements for research participation of children based on defined categories of potential risk and benefit of the research. The categories of research based on assessment on potential risks and benefits:

- 1) No greater than minimal risk, where minimal risk means “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests”
- 2) Greater than minimal risk and presenting the prospect of a direct benefit to the child, in which the anticipated benefit justifies the risk and is at least as favorable as that of alternative approaches
- 3) A minor increase over minimal risk with no prospect of a direct benefit to the subject, but likely to yield generalizable knowledge about the child’s disorder or condition that is of vital importance for the understanding or amelioration of the disorder or condition AND the intervention or procedure presents experiences to the child that are reasonably commensurate with those in the child’s actual or expected medical, dental, psychological, social, or educational situations.
- 4) Any other research, including research that poses more than a minor increase over minimal risk (for research in the United States and subject to the regulations, requiring the approval of the Secretary of Health and Human Services following consultation with a panel of experts and following publication and public comment).

**APPENDIX C - INFORMATION TO BE INCLUDED IN THE CONSENT DOCUMENT**

Informed consent forms provide written documentation of an ongoing and interpersonal process. Information to be included in consent forms is listed below.\*

- 1) A statement that the study involves research; identification of the research sponsor(s), principal investigator(s), and institution(s) performing the research;
- 2) An explanation of the purpose of the research, an invitation to participate and explanation of why the subject was selected, and the expected duration of the subject’s participation;
- 3) A description of procedures to be followed and identification of which procedures are investigational and which might be provided as standard care to the subject in another setting. Use of research methods such as randomization and placebo controls should be explained;
- 4) A description of any foreseeable risks or discomforts to the subject, an estimate of their probability and magnitude, and a description of what steps will be taken to minimize or prevent them; as well as acknowledgement of potentially foreseeable risks;
- 5) A description of any benefits to the subjects or to others that may reasonably be expected from the research, and an estimate of their likelihood;

- 6) A disclosure of any appropriate alternative procedures or courses of treatment that might be advantageous to the subject;
- 7) A statement, when applicable, that participation in the research may limit the subject's eligibility for participation in future research studies.
- 8) A statement describing to what extent records will be kept confidential, including examples of who may have access to research records such as hospital personnel, the FDA, the drug sponsors;
- 9) For research involving more than minimal risk, an explanation and description of any compensation and any medical treatments that are available if subjects are injured through participation; where further information can be obtained, and whom to contact in the event of a research-related injury;
- 10) An explanation of whom to contact for answers to questions about the research and the research subject's rights;
- 11) A statement disclosing the research sponsor(s).
- 12) A statement that research is voluntary and that refusal to participate or a decision to withdraw at any time will involve no penalty or loss of benefits to which the subject is otherwise entitled;
- 13) A concluding statement indicating that the subject is making a decision whether or not to participate, and that his/her signature indicates that he/she has decided to participate having read and discussed the information presented.

\* From the National Institutes of Health Intramural Clinical Research Program, with minor modification.

# **HUMAN ISLET TRANSPLANTATION**

## **BACKGROUND**

JDRF is committed to the goal of accomplishing successful human islet transplantation in diabetes. Through its islet isolation and distribution facilities and centers for clinical islet transplantation as well as partnerships with NIH to support islet transplantation, JDRF has made and will continue to make a major commitment to this line of investigation.

In the past two years, significant advances in islet transplantation have occurred, particularly the recently reported successful Edmonton protocol. These advances have expanded the potential scientific and clinical opportunities in islet transplantation. This document is intended to outline JDRF guidelines concerning future research support in this area.

## **INDEPENDENT RESEARCH SUPPORT FROM JDRF**

JDRF will continue to support cutting edge research that will lead to successful human islet transplantation and therefore encourages applications that propose new, innovative ideas and that focus on unanswered questions. Areas of interest include, but are not limited to: 1) improving islet isolation, survival and stability; 2) determining whether islets can be stored and/or shipped to other sites; 3) evaluating short term anti-inflammatory therapies as a means of improving early engraftment; 4) evaluating alternative sites for transplantation; 5) evaluating effects of in vitro islet manipulations; 6) development of new, innovative and safe clinical protocols.

## **ESTABLISHMENT OF NEW PROGRAMS**

Although JDRF recognizes the desirability of establishing new programs for human islet transplantation worldwide, investigators are encouraged, when possible, to seek alternative sources of funds to initiate these efforts before applying to JDRF for funding. JDRF welcomes applications for expansion or extension of existing efforts. In general, investigators should provide evidence of competence by successfully performing several islet transplants using “standard” protocols. This “entry-level” criterion has been established in order to expedite the translation of research to clinical practice. Source of pancreata should also be addressed in the application.

## **IMMUNE TOLERANCE NETWORK**

JDRF is committed to supporting the work of the Immune Tolerance Network (ITN). Investigators interested in pursuing tolerance protocols for islet transplantation are encouraged to also submit their applications to the ITN. However, JDRF recognizes that the ITN may not be able to accommodate all ideas or groups and, therefore, JDRF will accept research applications for tolerance induction. Applicants are encouraged to take advantage of the wealth of information available through the ITN concerning clinical islet transplantation in preparing applications to JDRF.

## **REVIEW PROCEDURES**

JDRF will follow its usual review procedures and applications will be independently evaluated either through our current review group or through an ad hoc review panel.

## **LETTERS OF INTENT**

Investigators proposing studies with budgets in excess of USD 1 million over three years must submit letters of intent to JDRF. Letters of intent should include the following information:

- 1) Project title;
- 2) Name, affiliation, address, phone and fax numbers and email address of the principal investigator;

- 3) Identities of other key personnel and participating institutions and a description of their roles in the project;
- 4) Goals, hypothesis to be tested and specific aims of the study;
- 5) Brief description of the scientific rationale of the proposed study;
- 6) Source of islets for transplantation and availability of pancreata;
- 7) Evidence of competence in human islet transplantation using “standard” protocols;
- 8) Estimated budget.


The letter of intent should not exceed four pages and should be submitted via [proposalCENTRAL](#).

Applicants will be notified within (6) weeks whether to submit a full application and proposal.

## **CONTACTS**

Question regarding JDRF guidelines on human islet transplantation or letters of intent should be directed to:


Julie Greenstein, Ph.D.

 212-479-7682

 [jgreenstein@jdrf.org](mailto:jgreenstein@jdrf.org)

or

Robert Goldstein, M.D., Ph.D.

 212-479-7523

 [rgoldstein@jdrf.org](mailto:rgoldstein@jdrf.org)

# **HUMAN EMBRYOS IN STEM CELL RESEARCH**

## **UPDATED FEBRUARY 2003**

### **PURPOSE OF POLICY**

The purpose of JDRF's Policy Statement/Guidelines for the Use of Human Embryos in Stem Cell Research is to be clear regarding research to derive human embryonic stem (hES) cells.

### **STATEMENT OF POLICY**

JDRF funds research for the derivation of hES from excess embryos created by in vitro fertilization (IVF) for reproductive purposes. This includes stored embryos that are no longer needed for reproductive purposes and embryos determined to be clinically unsuitable for uterine implantation.

Applicants who propose research to derive hES cells from excess human embryos should address within the research application:

- a) The source of embryos
- b) The basic procedures of the protocol for the derivation of hES, including embryo screening protocols
- c) A plan for obtaining donor informed consent for the research use of embryos; submission of draft patient information and consent documents is required
- d) A statement as to why the use of human embryos is necessary to conduct the research
- e) In addition to review by the JDRF Medical and Science Review Committee and Lay Review Committee, all applications that propose the derivation and/or use of human pluripotent stem cells will be subject to review by a JDRF oversight panel to ensure that the ethical issues addressed in the guidelines are fully met. Prior to the initiation of funding of approved applications, JDRF will require:
  - f) Documentation of approval by an institutional review board (IRB) or the international local ethics review committee equivalent to ensure that appropriate protections are in place and will be followed.
  - g) Sample patient information and informed consent forms
  - h) Documentation of required regulatory approvals (e.g., national and/or local licensing agencies)
  - i) Assurance of the sponsoring institution that the research is in accord with local laws and regulations
  - j) Warrant that any research tools (for example cell lines, genetic arrays) derived from the research will be available internationally to other academic groups without restrictive material transfer agreements

### **REQUIREMENTS**

#### ***Conditions for Stem Cell Research Using Excess Human Embryos***

To ensure the ethical conduct of such research, it should satisfy the following conditions:

- a) There should be clear separation between the decision to create embryos for reproductive purposes and the decision to donate excess embryos for stem cell research.
- b) The research consent process should allow for timely, fully informed, and voluntary consent from the persons for whom the embryos were created for reproductive purposes.
- c) There should be no financial inducements, monetary or otherwise, for the donation of embryos for research.
- d) The attending fertility physician treating the potential embryo donors should make all clinical treatment decisions independent of and uninfluenced by any potential research use of excess embryos. The attending fertility physician and the researcher proposing to use embryos for human stem cell research should not be one and the same.

- e) A clinical embryo screening protocol should be in place. This protocol should utilize and specify defined criteria, and the implementation of those criteria should not be influenced by the potential research use of embryos.
- f) Embryos used for research should not be maintained intact in culture beyond 14 days post-fertilization, the internationally accepted time limit.

#### ***Required Elements of Informed Consent for Stem Cell Research Use of Excess Embryos***


Informed consent for the use of excess embryos for human stem cell research should include the following:

- a) A statement that only embryos that are unsuitable for or in excess of clinical use will be used in research
- b) A statement that the embryos will be used to derive human pluripotent stem cells for research
- c) A statement that embryos donated will not be transferred to any woman's uterus and will not survive the human pluripotent stem cell derivation process
- d) A statement that the research is not intended to provide direct medical benefit to the donor
- e) A statement that research donation is voluntary and that a decision to consent or refuse to participate in research will not affect the quality of clinical care
- f) A statement as to whether information that could identify the donors of the embryos, directly or indirectly through identifiers linked to the donors, will be removed prior to the derivation or the use of human pluripotent stem cells
- g) A statement that derived cells/and or cell lines may be kept for many years and may be shared with multiple researchers at multiple research institutions
- h) A disclosure of the possibility that the results of the research on the human pluripotent stem cells may have commercial potential, and a statement that the donor will not receive financial or any other benefits from any such future commercial development
- i) A statement that human pluripotent stem cells derived from the research may be used for human transplantation research and that the donation is made without any restriction or direction regarding the individual(s) who may be the recipients(s) of transplantation of the cells derived from the embryo
- j) An individual should be identified who can be consulted for independent advice on the research donation of embryos

#### **CONTACTS**

Question regarding JDRF guidelines on human embryos in stem cell research should be directed to:

Adrienne Wong, Ph.D.

 212-479-7642

 [awong@jdrf.org](mailto:awong@jdrf.org)

# **HUMAN FETAL TISSUE IN RESEARCH**

## **UPDATED FEBRUARY 2003**

### **PURPOSE OF POLICY**

The purpose of the JDRF Policy Statement/Guidelines for the Use of Human Fetal Tissue in Research is to be clear regarding research using human cadaveric fetal tissue and embryonic germ cells derived from human cadaveric fetal tissue.

### **STATEMENT OF POLICY**

JDRF's long-standing position has been to support research using human fetal material that conforms to state and federal statutory and regulatory requirements. Consistent with these requirements, JDRF requires that for all research using human cadaveric fetal tissue, the decision to donate fetal tissue for research should occur independent of and subsequent to the decision to terminate a pregnancy and that there should be no inducements, financial or otherwise, for the research donation.

Applicants who propose research using human fetal tissue should address within the research application:

- The source of fetal tissue
- The basic procedures of the research protocol using fetal tissue
- A plan for obtaining donor informed consent for the research use of human fetal tissue; submission of draft patient information and consent documents is required
- A statement as to why this source of tissue is necessary to conduct the research

Prior to the initiation of funding of approved applications, JDRF will require:

- Documentation of approval by an institutional review board (IRB) or the international local ethics review committee equivalent to ensure that appropriate protections are in place and will be followed
- Sample patient information and informed consent forms
- Assurance of the sponsoring institution that the research is in accord with local laws and regulations
- Warrant that any research tools (for example cell lines, genetic arrays) derived from the research will be available internationally to other academic groups without restrictive material transfer agreements

### **REQUIREMENTS**

#### ***Required Elements of Informed Consent for Research Use of Human Fetal Tissue***

Informed consent for the use of fetal tissue for research should include the following:

- a) A statement that fetal tissue obtained from an elective termination of pregnancy may be used for research
- b) A statement that the research is not intended to provide medical benefit to the donor
- c) A statement that the research donation is voluntary and that a decision to consent or refuse to participate in research will not affect the quality of clinical care
- d) A statement that the donor will not receive financial or any other benefits from the research or any future commercial products
- e) In cases where the research will derive cell lines, a statement as to whether information that could identify the tissue donor, directly or indirectly through identifiers linked to the donor, will be removed prior to the derivation or use of the cell lines
- f) In cases where the fetal tissue or derived cell lines may be used in clinical transplantation protocols, a statement that the research is to occur altruistically; that is, the donor may not direct into whom the tissue or derived cells may be transplanted

- g) In cases where the fetal tissue or derived cell lines may be used in clinical transplantation protocols, a statement as to whether the identity of the donor will be made known to the recipient
- h) A statement that derived cells/and or cell lines may be kept for many years and may be shared with multiple researchers at multiple research institutions
- i) The prospect of commercial interests in the cells or cell lines; that is, that there is a possibility that the results of this research may have commercial potential

***Statement of Policy: Research Use of Human Fetal Tissue to Derive Human Embryonic Germ (EG) Cells***

JDRF recognizes that existing federal (U.S.) policy permits research involving the derivation and use of embryonic germ (EG) cells from human cadaveric fetal tissue, and such research is eligible for federal funding. JDRF also recognizes, however, that existing statutes and regulations may not clearly specify that the ethical safeguards that exist for fetal tissue transplantation also apply to the derivation and use of EG cells from cadaveric fetal tissue.

JDRF considers EG cells to be a form of human fetal tissue. As such, JDRF may fund research proposals that derive and/or use EG cells following elective termination of pregnancy provided that the research meets the requirements for human fetal tissue research generally (see above). In addition to review by the JDRF Medical Science Review Committee and Lay Review Committee, all applications that propose the derivation and/or use of human pluripotent stem cells will be subject to review by a JDRF oversight panel to ensure that the ethical issues addressed in the guidelines are fully met.

Applicants who propose research to derive human EG cells from cadaveric human fetal tissue should address within the research application:

- The source of fetal tissue
- The basic procedures of the protocol for the derivation of human EG cells
- A plan for obtaining donor informed consent for the research use of human fetal tissue; submission of draft patient information and consent documents is required
- A statement as to why this source of tissue is necessary to conduct the research

Prior to the initiation of funding of approved applications, JDRF will require

- Documentation of approval by an institutional review board (IRB) or the international local ethics review committee equivalent to ensure that appropriate protections are in place and will be followed
- Sample patient information and informed consent forms
- Assurance of the sponsoring institution that the research is in accord with local laws and regulations
- Guarantee that any research tools (for example cell lines, genetic arrays) derived from the research will be available to other academic groups without restrictive material transfer agreements


***Required Elements of Informed Consent for Research Use of Human Fetal Tissue***

Informed consent for the use of fetal tissue for research should include, as applicable for the proposed research, all elements listed (a-i) on pp.1-2. In addition, informed consent should include a statement that fetal tissue obtained from an elective termination of pregnancy may be used for research involving embryonic germ cells to derive human pluripotent stem cell lines.

## CONTACTS

Question regarding JDRF policy/guidelines on research use of human fetal tissue should be directed to:

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