



*dedicated to finding a cure*

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

**Updated October 2009**

**\*Please see updated Research Plan guidelines under each grant mechanism.\***

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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, 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?
Industry Discovery and Development Partnership	Open	2	Y*
Regular Research Grant	\$165,000	3	N
Innovative 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	\$42,868 - \$52,960**	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 (NIH) 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 may receive written critiques, but will not receive a summary.)

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 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. JDRF follows U.S. National Institutes of Health (NIH) salary guidelines for Principal Investigators and Post-Doctoral Fellows. JDRF guidelines are adjusted when the new NIH guidelines go into effect.

### **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. For Post-Doctoral and Advanced Post-Doctoral Fellowships, Other Support information should be provided *for the Sponsor only*.

### **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.**

## **HUMAN SUBJECT RESEARCH APPLICATION REQUIREMENTS**

All applications proposing research with human subjects, regardless of grant mechanism, must follow the [Human Subject Research Guidelines](#). **Human Subject applications without appropriate supplemental information 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](#).

If you are unsure if your proposed study involves human subjects, please [click here](#) to access the NIH guidelines addressing human subject research.

## **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) An introduction (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
- Advanced Postdoctoral Fellowships
- Career Development Awards
- Early Career Patient-Oriented Diabetes Research Awards
- Postdoctoral Fellowships
- 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.

## 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). Applicants must log onto proposalCENTRAL at <http://proposalcentral.altum.com/default.asp?GMID=16>, using their pC username and password, and select the appropriate application from the list of JDRF funding opportunities.



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

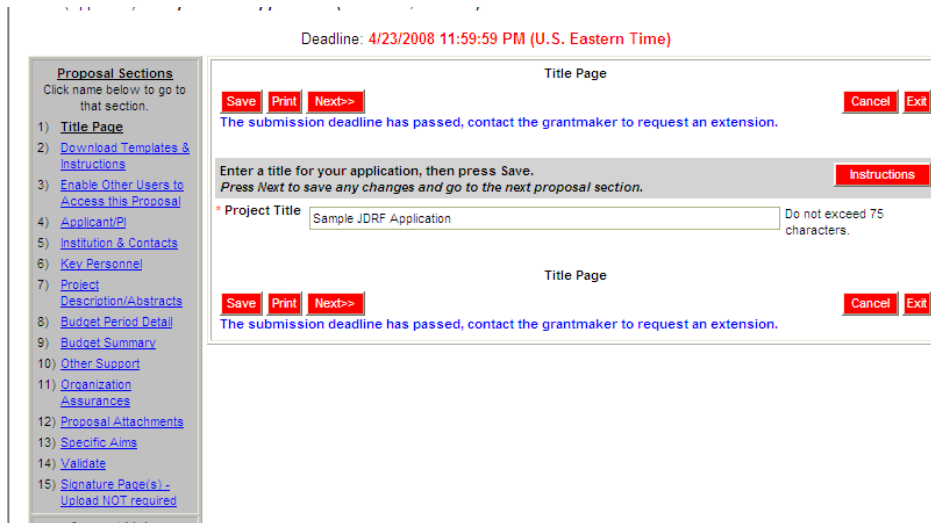
Grant Opportunities - Deadlines displayed in U.S. Eastern Time

Juvenile Diabetes Research Foundation

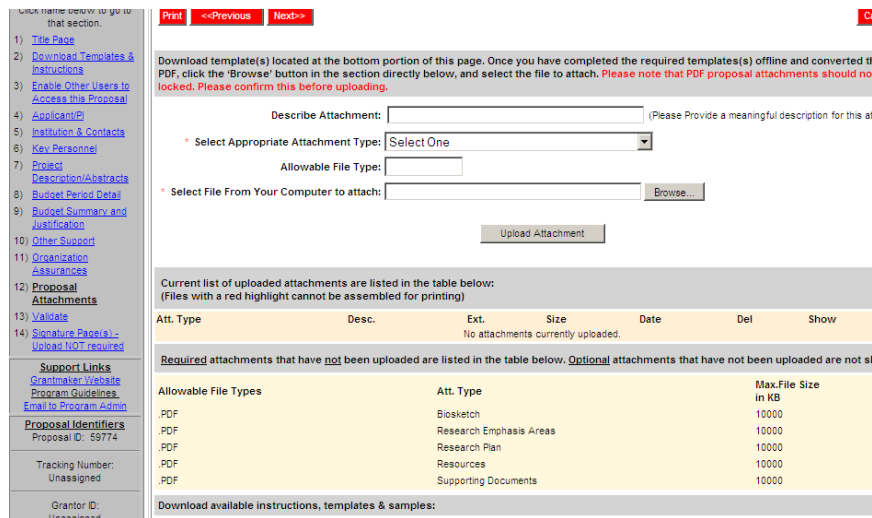
If you would like to check for a specific grant making organization, you may utilize the drop-down list above. To see all available opportunities, select "Show All"

Grant Maker	Programs (Click for Guidelines)	LOI Deadline	Proposal Deadline	Contact Information	FAQ
<a href="#">Juvenile Diabetes Research Foundation</a>	<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>	
<a href="#">Juvenile Diabetes Research Foundation</a>	<a href="#">PPG Individual Core Grant</a>		9/15/2008 11:59:59 PM	<a href="#">Grants Administrator</a>	
<a href="#">Juvenile Diabetes Research Foundation</a>	<a href="#">PPG Individual Project Grant</a>		9/15/2008 11:59:59 PM	<a href="#">Grants Administrator</a>	
<a href="#">Juvenile Diabetes Research Foundation</a>	<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>	
<a href="#">Juvenile Diabetes Research Foundation</a>	<a href="#">Scholar Award</a>		12/1/2008 11:59:59 PM	<a href="#">Grants Administrator</a>	
<a href="#">Juvenile Diabetes Research Foundation</a>	<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) Complete each of the proposal sections listed in the table of the left hand side of the screen (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 to continue to the next section.



- 2) Click on the [Proposal Attachments](#) link and download each proposal section template. To upload, select, one at a time, the appropriate attachment type from the drop-down list and use the “browse” function to insert the proposal section file. An applicant may also enter information in the ‘Describe Attachment’ field, but this is not required. Finally, click the “upload attachment button” to complete the process.



- 3) To check for any missing required information or files, click the 'Validate' button in the Validate section of the proposal. All missing required information will be listed on the screen. Please correct any missing information before submitting.
- 4) To complete the online submission, click the “submit proposal” button. You must click the “submit proposal” button to formally submit your application to JDRF.

## 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). **Please note that PDF proposal attachments should not be locked. Please confirm this before uploading to your application.**

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 application and go to the section from which you downloaded the template
- Enter your own description of the file in the “Describe Attachment” field (optional)
- Choose from the drop-down 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 Research Plan 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 include figures, charts, and tables.**

### 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.

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

## SECTION 2: GRANT MECHANISMS DESCRIPTIONS

### REGULAR GRANTS

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#### REGULAR RESEARCH GRANTS

**Note:** if your project involves human subject research, click [here](#).

##### 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.

##### Proposal

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

##### Research Plan

The research plan may not exceed 12 pages, including figures and tables. Please note that the 12-page limit includes narrative items a through d as described below. 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 must be incorporated in the 12-page limit without exception. Applications with research plans exceeding the page limit will not be reviewed.**

##### Evaluation

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. Please see JDRF's [budget guidelines](#) for details.

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 GRANTS

**Note: if your project involves human subjects research, 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.

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

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

### Research Plan

The innovative grant research plan may not exceed 3 pages, including figures and tables, and preliminary studies are not required. Please note that the 3-page limit includes narrative items a through d as described below. The research plan must be organized as follows: a) Specific Aims; b) Background and Significance to Type 1 Diabetes; c) Preliminary Studies (if available); d) Research Design and Methods; e) Literature Cited (no page limit). **All information in items a through d must be incorporated in the 3-page limit without exception. Applications with research plans exceeding the page limit will not be reviewed.**

### Evaluation

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) Innovation
- 2) Plausibility of underlining premise, goal or hypothesis
- 3) Feasibility of experimental approach and completing in one year
- 4) Relevance to the objectives of JDRF
- 5) Qualifications and research experience of the principal investigators and collaborators
- 6) Availability of resources and facilities necessary for the project
- 7) Appropriateness of the proposed budget in relation to the proposed research

### **Terms of the Award**

These grants provide one year of support for a maximum of USD 100,000 in direct costs and indirect costs of 10%, for a total of USD 110,000. These grants are not renewable. A final progress report is due within 60 days following the close of the award.

**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

Note: if your project involves human subject research, click [here](#).

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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](#). See the [proposalCENTRAL templates](#) and the [Applicant Guidelines](#) sections for specific 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, including figures and tables. Please note that the 7-page limit includes narrative items a through f, as described below. 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 f must be incorporated in the 7-page limit without exception. Applications with research plans exceeding the page limit will not be reviewed.**

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 Plan 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, 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'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 (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 Research Plan.

### 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 & Stipend

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 (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. The purchase of a personal computer is allowed (up to USD 2,000) only during Year 1 of the award. Health insurance costs are permissible. The award is renewable for a second year pending submission and approval of a renewal application and progress report.

Table 2: Postdoctoral Fellowship Allowances

Years	Stipend	Research Allowance	Total
0	\$37,368	\$5,500	\$42,868
1	\$39,360	\$5,500	\$44,860
2	\$42,204	\$5,500	\$47,704
3	\$43,860	\$5,500	\$49,360
4	\$45,504	\$5,500	\$51,004
5	\$47,460	\$5,500	\$52,960

## 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](#). See the [proposalCENTRAL templates](#) and the [Applicant Guidelines](#) sections for specific requirements.

#### *Research Plan*

The advanced postdoctoral fellowship research plan may not exceed 7 pages, including figures and tables. Please note that the 7-page limit includes narrative items a through f, as described below. 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 (no page limit). **All information in items a through f must be incorporated in the 7-page limit without exception. Applications with research plans exceeding the page limit will not be reviewed.**

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. 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 (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 Research Plan.

### **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 & Stipend

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% 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 USD 90,000 per year, can be used for travel to scientific meetings (up to USD 2,000/year), journal subscriptions, books, training courses, laboratory supplies, or equipment (in Year 1 only). The purchase of a personal computer is allowed (up to USD 2,000) 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.

Table 2: Advanced Postdoctoral Fellowship Stipends

Years	Stipend
0	\$37,368
1	\$39,360
2	\$42,204
3	\$43,860
4	\$45,504
5	\$47,460
6	\$49,344
7+	\$51,552

### 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 USD 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](#). See the [proposalCENTRAL templates](#) and the [Applicant Guidelines](#) sections for specific 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 12 pages, including figures and tables. Please note that the 12-page limit includes narrative items a through d as described below. 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 12-page limit without exception. Applications with research plans exceeding the page limit will not be reviewed.**

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 as a Supporting Document and uploaded as a proposal attachment.

### **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 AWARDS

### 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](#). See the [proposalCENTRAL templates](#) and the [Applicant Guidelines](#) sections for specific requirements.

### Research Plan

The early career patient-oriented research plan may not exceed 12 pages, including figures and tables. Please note that the 12-page limit includes narrative items a through d as described below. 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 f must be incorporated in the 12-page limit without exception. Applications with research plans exceeding the page limit will not be reviewed.**

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. This Department Head Statement must be included as a Supporting Document and uploaded as a proposal attachment.

### 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, including indirect costs. 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.

# ACADEMIC RESEARCH & DEVELOPMENT COOPERATIVE AGREEMENTS (formerly Academic R&D Grants, PPGs, and CIRGs)

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## SINGLE-PROJECT ACADEMIC R&D COOPERATIVE AGREEMENTS

### Description

JDRF's Academic R&D Cooperative Agreements were created to provide research funding for single or multiple investigators to address critical gaps and challenges and potential breakthroughs in Type 1 diabetes research. The Cooperative Agreement is a partnership between Investigator(s) and JDRF Scientific Staff to help address roadblocks and accelerate JDRF's mission through support of cutting-edge scientific investigation. Further, this mechanism embodies cooperative development of a research plan, interim quarterly reporting on milestones and interaction with JDRF staff prior to and during the award period. The budget and duration of funding are variable and continued funding is based on satisfactory effort and quarterly progress on milestones. Submission of a proposal requires permission from JDRF and is initiated with a [Project Concept](#) submitted to the appropriate [JDRF Research Staff](#).

Project Concepts meeting JDRF selection criteria will be invited to submit a formal Letter of Intent (LOI). The letter of intent is distributed to scientific experts for initial comments. JDRF will make a decision whether or not to invite the applicant to prepare and submit of a full research application. Research applications are by invitation only. Each stage of the application will be developed by the investigator in partnership with JDRF staff and with input from JDRF volunteer leadership.

In addition, JDRF is expanding its Academic Research and Development (Academic R&D) Cooperative Agreement mechanism to incorporate the former Program Project Grants (PPG) and Clinical Investigational Research Grants (CIRG).

### Submissions

#### Step 1: Project Concept

An investigator wishing to submit a Project Concept may download and complete the standard form by clicking [here](#). Send the completed form to the appropriate [JDRF staff](#). Project Concepts are selected on the basis of programmatic fit and robustness of the concept. In addition, projects that hold a prospect for transformative breakthroughs that prevent, treat or cure Type 1 diabetes will be given top priority. Project concepts can be submitted at any time. Applicants will be notified of the outcome of the Project Concept review.

#### Step 2: Letter of Intent

1. If the Project Concept is accepted, the Scientific Staff of the relevant program area will contact the applicant to develop a Letter of Intent document. The applicant will be authorized by JDRF to access the Letter of Intent template on proposalCENTRAL. The standardized Letter of Intent requires an outline of the project objectives, an overview of the research field, the specific aims and the approach for each aim. The Letter of Intent is discussed internally and reviewed by scientific experts in the field. The applicant may be requested to submit additional information to the Letter of Intent.
2. The decision to invite a full proposal is based on scientific/technical merit, gap-filling nature, breakthrough or paradigm-shifting potential, strategic portfolio fit, and competing opportunities.

#### Step 3: Research Application

1. The Scientific Staff works collaboratively with the investigator or investigator team to develop a full application in accordance with JDRF strategic objectives.
2. All research applications are submitted and reviewed using proposal central.

3. The complete and submitted application is reviewed by scientific experts and written critiques are received by the staff, generally in 4-6 weeks.
4. The reviewers' critiques will be shared with the applicant. The applicant may submit a rebuttal that addresses the concerns raised by the reviewers.
5. The entire application and review materials are deliberated the JDRF Lay committees. Final approval is made by the Executive Committee.
6. All grants involving human subject research will undergo a final review by the JDRF Protocol Review Committee prior to final approval by the Executive Committee. To determine if your research qualifies as Research on Human Subjects and for additional information on the related review process, please review JDRF's [Application Guidelines](#).

### **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

### **Terms of the Award**

Available funding for the Academic R&D Award will be reviewed on a per-application basis. Projects will be milestone-driven, require teleconferences with the Scientific Staff to discuss project progress and research findings on a quarterly basis. In addition to quarterly reports, 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. Projects are no more than 3 years duration. Support beyond 3 years will be determined based on a detailed scientific review of the accomplishments and future plans of the Project. Decisions on continued funding are made by the Program Director in consultation with Senior Management based on progress on milestones. 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.

### **Research Application**

The [Project Concept form](#) is available to all applicants on the JDRF website. Letter of Intent and Research Applications are available by invitation only via the proposalCENTRAL website.

If the applicant's LOI has been approved by JDRF, the applicant will be invited to submit a full research application. The applicant will be authorized to access and electronically submit the completed application via the proposalCENTRAL website.

**Note: if your project involves human subject research, click [here](#).**

## MULTI-PROJECT ACADEMIC R&D COOPERATIVE AGREEMENTS

**Note:** *This funding mechanism replaces the former PPG funding mechanism. Applicants who have been invited to submit a JDRF Letter of Intent (LOI) for a multi-project Academic R&D may only submit applications under this category.*

### Description

JDRF Academic R&D Cooperative Agreement for multiple 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 major challenges, potential breakthroughs, or persistent obstacles to progress along the various paths to prevent, treat or cure Type 1 diabetes and its complications. JDRF's Academic R&D Cooperative Agreements were created to provide research funding for single or multiple investigators to address critical gaps and challenges and potential breakthroughs in Type 1 diabetes research. The Cooperative Agreement is a partnership between Investigator(s) and JDRF Scientific Staff to help address roadblocks and accelerate JDRF's mission through support of cutting-edge scientific investigation. Further, this mechanism embodies cooperative development of a research plan, interim quarterly reporting on milestones and interaction with JDRF staff prior to and during the award period. The budget and duration of funding are variable and continued funding is based on satisfactory effort and quarterly progress on milestones. Submission of a proposal requires permission from JDRF and is initiated with a [Project Concept](#) submitted to the appropriate [JDRF Research Staff](#).

A central theme highly relevant to the priority areas of research for JDRF is required and must include a set of clearly defined goals that can be met within a 3-year period. In most cases, JDRF Multi-Project Academic R&D Cooperative Agreements 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 Multi-Project Academic R&D Cooperative Agreements will be considered. Multi-Project Academic R&D Cooperative Agreements may 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 Project principal investigator is required. Generally, administration of the 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 Multi-Project Academic R&D Cooperative Agreement application.

Project Concepts meeting JDRF selection criteria will be invited to submit a formal Letter of Intent (LOI). The letter of intent is distributed to scientific experts for initial comments. JDRF will make a decision whether or not to invite the applicant to prepare and submit of a full research application. *Research applications are by invitation only.* Each stage of the application will be developed by the investigator in partnership with JDRF staff and with input from JDRF volunteer leadership.

In addition, JDRF is expanding its Academic Research and Development (Academic R&D) Cooperative Agreement mechanism to incorporate the former Program Project Grants (PPG) and Clinical Investigational Research Grants (CIRG).

**Note: if your project involves human subject research, click [here](#).**

### Submissions

Please follow submission steps 1 through 3 as outlined above and the eligibility, terms of the award, and research application as described for [Single-Project Academic R&D Cooperative Agreements](#).

## Research Application

If the applicant's LOI has been approved by JDRF, the applicant will be invited to submit a full research application. The applicant will be authorized to access and electronically submit the completed application via the [proposalCENTRAL website](#).

Upon approval of the LOI, only the Multi-Project Academic R&D Cooperative Agreement Overview application will become automatically available. The Principal Investigators of individual Projects & Cores must complete separate online applications on the [proposalCENTRAL website](#) for each Multi-Project Academic R&D Cooperative Agreement Individual Project/Core.

## Proposal Title

The titles for each individual Project/Core application MUST begin with the last name of the Multi-Project Academic R&D 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 Multi-Project Academic R&D Director is John Doe:

Multi-Project Academic R&D Overview Title: "DOE Overview: Mechanisms to develop a cure for Type 1 Diabetes Mellitus"

Multi-Project Academic R&D Project 1 Title: "DOE Project 1: Regulators in Beta Cell Function"

Multi-Project Academic R&D Project 2 Title: "DOE Project 2: Inhibitors of immune deficiency"

Multi-Project Academic R&D Core A Title: "DOE Core A: Mouse Core"

## Review

The overall Project and 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 overall Project and whether it should be included. Reviewers will be provided with the full application to assist them in their evaluation. As with the [single project Academic R&D](#), reviewer comments will be shared with the Investigator team and given an opportunity to respond to the commentary.

### ***Review of the Academic R&D Cooperative Agreement for Multiple Projects***

The relationship and contributions of each individual research project and core to the overall theme of the Multi-Project Academic R&D Cooperative Agreement 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, critical gaps and challenges, or novel paradigms in Type 1 diabetes
- Relevance to the objectives and research emphasis areas of JDRF
- Scientific, technical, or medical significance of the Multi-Project Academic R&D Cooperative Agreements
- Scientific merit of the Multi-Project Academic R&D Cooperative Agreements 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 Multi-Project Academic R&D Cooperative Agreements 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 Multi-Project Academic R&D Cooperative Agreement?
- Investigators:
  - Assessment of the leadership and scientific ability of the principal investigator
  - 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 Multi-Project Academic R&D Cooperative Agreement: 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 Multi-Project Academic R&D Cooperative Agreement;
  - 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:
  - Organizational aspects of the Multi-Project
  - Assessment of the plans for meetings, other interactions, and exchange of data, material and techniques.
  - Effect of geographical distribution of the members.
- Institutional and other sources of support:
  - Institutional commitment
  - Impact of the project on the institutions involved in terms of research priorities of the institution, financial support, time protection, and laboratory space and equipment
- Other sources of financial support for the request,
  - Cost-sharing arrangements with the sponsoring institution(s),
  - Industry (keeping in mind that university-industry collaborations are encouraged),
  - 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.

## ACADEMIC R&D COOPERATIVE AGREEMENTS FOR HUMAN SUBJECTS RESEARCH

**Note:** *This funding mechanism replaces the former CIRG funding mechanism. Only applicants who have been invited to submit a JDRF Letter of Intent (LOI) for Clinical Academic R&D may submit applications under this category.*

### Description

JDRF Academic Research and Development Cooperative Agreements for Human Subjects Research are intended to support research programs that qualify under the JDRF clinical review process. This funding mechanism is intended to support early-stage clinical trials to test 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 markers) for diabetes and its complications. Applications for Clinical Academic Research and Development Grants must be goal oriented and closely focused on the JDRF mission.

JDRF's Academic R&D Cooperative Agreements were created to provide research funding for single or multiple investigators to address critical gaps and challenges and potential breakthroughs in Type 1 diabetes research. The Cooperative Agreement is a partnership between Investigator(s) and JDRF Scientific Staff to help address roadblocks and accelerate JDRF's mission through support of cutting-edge scientific investigation. Further, this mechanism embodies cooperative development of a research plan, interim quarterly reporting on milestones and interaction with JDRF staff prior to and during the award period. The budget and duration of funding are variable and continued funding is based on satisfactory effort and quarterly progress on milestones. Submission of a proposal requires permission from JDRF and is initiated with a [Project Concept](#) submitted to the appropriate [JDRF Research Staff](#).

Project Concepts meeting JDRF selection criteria will be invited to submit a formal Letter of Intent (LOI). The letter of intent is distributed to scientific experts for initial comments. JDRF will make a decision whether or not to invite the applicant to prepare and submit of a full research application. Research applications are by invitation only. Each stage of the application will be developed by the investigator in partnership with JDRF staff and with input from JDRF volunteer leadership.

### Submissions

Please follow submission steps 1 through 3 as outlined above and the eligibility, terms of the award, and research application as described for [Single-Project Academic R&D Cooperative Agreements](#).

### Research Application

If the applicant's LOI has been approved by JDRF, the applicant will be invited to submit a full research application. The applicant will be authorized to access and electronically submit the completed application via the proposalCENTRAL website.

All applications involving human subjects research must include supplemental information to address subject safety, study design and investigational product information. More details can be found in the [Human Subject Research Guidelines](#).

All applications that receive a funding recommendation after scientific review will be transferred to the [Protocol Committee](#) where a subsequent review of the protocol and supporting documents will be performed.

## Review Considerations

### *Scientific Review*

Academic R&D Cooperative Agreement for Human subjects Research will be evaluated in a two-stage process. The first review is conducted by a committee of clinical investigators for scientific merit and second review by the JDRF Protocol committee for clinical standard of care for the proposed patient population and for adherence to Good Clinical Practice. The scientific 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.

**More information can be found in the [JDRF Human Subject Research Guidelines](#) and in the [JDRF Protocol Review Committee](#) section.**

## SPECIAL GRANTS

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### INDUSTRY DISCOVERY & DEVELOPMENT PARTNERSHIPS

**Note:** Companies interested in applying for JDRF Industry Discovery & Development Partnerships (IDDP) are encouraged to first contact Dr. Richard A. Insel, Executive Vice President of Research:

 [rinsel@jdrf.org](mailto:rinsel@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. JDRF also 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. 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.

#### **Application**

JDRF encourages interested companies to initially contact Dr. Richard A. Insel, Executive Vice President of Research:

 [rinsel@jdrf.org](mailto:rinsel@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. Please [click here](#) to access the LOI template.

## SCHOLAR AWARDS

### 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 AWARDS

### 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](#).

### Research Plan

The high-priority, short-term bridge award research plan may not exceed 2 pages, including figures and tables, and should indicate any changes in scope from the original application. **Applications with research plans exceeding the page limit will not be reviewed.**

## 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.**

JDRF supports human subject research that seeks to translate basic research discoveries to cure, prevent and/or reverse Type 1 diabetes and its complications. Applicants should follow general guidelines for research applications and should include the information requested below about the human subject study design, safety monitoring, and ethical requirements regarding human subject research participation.

## HUMAN SUBJECT RESEARCH GUIDELINES

### Human Subject Application Requirements

All applications involving human subject research should address study design as stated below.

**NOTE: All templates referenced below are available with the application on proposalCENTRAL**

#### *Human Subject Protocol Synopsis Requirement*

All applications that propose human subject studies must include a Protocol Synopsis. Use of the JDRF Protocol Synopsis template is not required; however, at a minimum, all information requested on the template must be included within your study synopsis.

#### *Human Subject Research Plan*

All applications that propose research with human subjects must include a Human Subject Research Plan (HSRP). All eight items in the HSRP template must be addressed and the HSRP should not exceed three pages. Please refer to the following instructions for completing the HSRP:

- 1. Criteria for subject inclusion/exclusion, especially those pertinent to subject protection:**  
Describe the proposed involvement of study subjects, including patients and healthy control subjects, stating their anticipated number, age range, gender, ethnic/racial background, and health status. Identify criteria for inclusion or exclusion of any subpopulation, including children and adolescents.
- 2. Potential benefits and risks to subjects, plans to minimize risks, and knowledge to be gained from the study:**

For each proposed intervention and proposed subject group, describe the following:

- The potential direct and indirect benefits to the individual subject and/or group of subjects.
- The potential risks (physical, psychological, social, legal, or other) to all study subjects, including the likelihood and seriousness of each risk.
- Potential risks to pregnant women and fetuses.

For research involving children and adolescents:

- Classify the level of 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 A in JDRF Human Subject Research Guidelines).
- 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 to be gained from the study results.

### **3. Monitoring study subject safety:**

Discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects for subjects. (Note a complete data safety-monitoring plan must be included for proposed human subject studies that are reviewed by the JDRF Protocol Review Committee. Please see information on “Documents Required for JDRF Protocol Review Committee” in the instructions for [JDRF Human Subject Research Guidelines](#)).

### **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 the 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 for study subjects:**

Describe any potential costs for study subjects and any incentives or remuneration that study subjects will receive by participating in the study, including compensation for injury incurred as a result of study participation.

For research studies that propose remuneration for participation of minors, state whether the remuneration is offered to the parents or their minor children.

### **6. Research subject informed consent process:**

Describe the process for obtaining subject informed consent, including 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 and adolescents, discuss plans for obtaining assent of minors.

When available, submission of a *draft* patient information and consent (assent) document is strongly recommended.

Guidelines for the informed consent document are provided in Appendix B below.

### **7. Potential conflicts of interest, including investigator plans to inform study subjects about any perceived conflicts:**

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

Include plans to inform study subjects about any perceived conflicts of interest.

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

For all key personnel, describe their education on the protection of human research subjects.

### **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.

### ***Supplemental Product Information Requirement***

Information regarding the therapeutic product(s) used as part of the human subjects research is required. Applicants proposing human subjects research that is non-interventional are not required to provide this information. You must complete the supplemental product information template for any human subject research using therapeutic product(s).

**NOTE: All templates referenced above are available with the application on proposalCENTRAL**

### ***Good Clinical Practice Guideline Requirement for JDRF-Funded Human Subject Grants***

All JDRF Human Subject Grants are expected to adhere to the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines Consolidated Guidance (ICH-E6).

Any request to deviate from GCP should be made in writing during initial grant submission.

### ***Standard of Care Requirements for JDRF-Funded Human Subject Grants***

All JDRF Human Subject Grants are expected to adhere to Current Standards of Care for treatment of diabetes. Acceptable standards include American Diabetes Association (ADA), American Association of Clinical Endocrinologists (AACE), International Society for Pediatric and Adolescent Diabetes (ISPAD), and European Association for the Study of Diabetes (EASD).

JDRF may, at its discretion, reference other treatment guidelines appropriate to the protocol being reviewed.

Any request to deviate from these requirements should be made in writing during initial grant submission.

### **General Information Regarding Protocol Review**

All human subject grants that have favorable MSRC reviews and have been recommended for funding will undergo a final review by the JDRF Protocol Review Committee. Funding for human subject grants will not be awarded until the protocol review process is completed.

The JDRF Protocol Review Committee conducts a clinical, statistical and ethics review of the JDRF Human Subject Research Plan, Data Safety Monitoring Plan and the IRB-ready protocol and informed consent document to evaluate the study strategy and execution of this strategy. It is strongly recommended that you speak with JDRF Program Director or delegate *prior to* finalizing your study documents. JDRF staff can assist investigators in creating documents that avoid review "hurdles" or "issues" based on previous protocol review outcomes. JDRF currently has resources available to assist clinical investigators in protocol development activities. We encourage investigators to explore these options to maximize the value of their research.

JDRF is prepared to provide concrete resources to assist investigators and expedite protocol development via provision of consulting expertise in trial design, statistical analysis, medical/protocol writing, etc.

### **Documents Required for Protocol Review Committee**

The following documents will be required for submission to the JDRF Protocol Review Committee. Note that some of these documents are part of the current application (HSRP, documentation of human subjects training of key grant personnel):

- IRB(or ethics committee)-ready protocol
- IRB (or ethics committee)-ready informed consent document
- JDRF Human Subject Research Plan
- Data Safety Monitoring Plan
- Product Information Form

Please note that IRB/Ethics Committee approval *is not required* for the JDRF Protocol Review Committee meeting to take place. It is strongly recommended that you seek IRB/Ethics Committee approval *after* the JDRF Protocol Review Committee meeting has taken place.

### **Documents Required Prior to Funding Release**

Prior to funding, the following information will be required:

- Documentation of IRB review and approval (or international local ethics board equivalent)
- Institutional assurance that the research is in accord with relevant national, state local and international law
- Copy of the FDA-IND letter (or country-equivalent), where applicable JDRF will require annual review of funded human subject investigation research. (Human Subject Studies requiring an FDA- IND or country-equivalent should complete the [Supplemental Product Information](#) template.) Consult JDRF staff if you have questions concerning INDs or other regulatory requirements.

Continued funding will be contingent on the researchers' ability to enroll subjects and to ensure subject safety

## **APPENDIX A - 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 B - 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

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# 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:

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# 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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