JDRF Juvenile Diabetes Research Foundation International

Dedicated to finding a cure

JDRF GRANT MECHANISM DESCRIPTIONS & GUIDELINES:

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For Special Requests for Applications go to: www.jdrf.org under *For Scientists* and *Information for Applicants*

JDRF (www.jdrf.org) is a global funding agency with a substantial proportion of its grants awarded outside of the United States. We encourage any and all qualified researchers interested in helping us overcome the scientific and clinical problems associated with type 1 diabetes and its complications to apply to JDRF for funding. Eligibility is determined by the quality of the research proposal and the opportunity it offers to move research closer to a cure.

JDRF has adopted a number of mechanisms to fund innovative science and clinical research aimed at accelerating progress toward the cure and prevention of type 1 diabetes and its complications, including Research Centers, Program Projects, Clinical Investigations, Regular and Innovative Grants, and Industry Grants. These award mechanisms are designed to help the JDRF build a research portfolio that serves our mission and provides the research community with the means to develop and prove new approaches to solving the problems of people with and at risk for type 1 diabetes and its complications. A summary of the key features of each award type is presented in Table 1.

TABLE 1: JDRF Research Grant and Fellowship Award Mechanisms

Award Type	Budget Cap (Annual)	Duration (Years)	LOI	Clinical Outcome
JDRF Center	$2,000,000	5	Y	Y
Program Project Grant	$660,000	3	Y	Y/N
Clinical Investigation Research Grant	$660,000	5	Y	Y
Industry Discovery and Development Partnership	Staged	2	Y	Y/N
Regular Research Grant	$165,000	3	N	Y/N
Innovative Grant	$110,000	1	N	Y/N
JDRF Scholar Award	$250,000	5	N	Y/N
Career Development Award	$150,000	5	N	Y/N
Early-Career, Patient-Oriented Diabetes Research Award	$150,000	5	N	Y
Advanced Postdoctoral Fellowship	$90,000	3	N	Y/N
Postdoctoral Fellowship	$42,496-52,492	2	N	Y/N

Applications will be accepted to support studies addressing one or more of the JDRF cure goals:

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

For more detailed information about JDRF priorities and areas of research funding focus, please see the Research Emphasis Areas announcement.

Potential applicants should note the following:

- As a general matter, JDRF will consider only research applications in its listed priority areas. However, new ideas that might not obviously fit described priorities but which may have potential to achieve one of our cure goals may be considered. Inquiries are encouraged and should be directed to:

Richard A. Insel, M.D.
rinsel@jdrf.org
212-476-7604

Or

Robert Goldstein, M.D., Ph.D.
rgoldstein@jdrf.org
212-479-7523

- 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 this principle, and must take steps in order to facilitate availability of data and samples.

- JDRF partners with various other national research organizations to leverage funds for diabetes research. Applicants are urged to explore all potential funding sources, including other private organizations, government initiatives and internationally supported consortia. The JDRF research program is intended to provide leadership in support of the development and proof of new approaches to unsolved diabetes-related scientific questions and clinical problems and in accelerating the application of research advances for clinical benefit.

- JDRF is committed to accelerating progress toward a cure for type 1 diabetes and its complications. We are also interested in well-designed research proposals that might be considered high risk because they challenge conventional paradigms or employ innovative methods or technologies. High-risk/high-impact or field-changing proposals are therefore encouraged.

IMPORTANT! APPLICATION REQUISITES & TIPS:

Applicants applying for any of the following award types need to begin their application by registering as a proposalCENTRAL™ User. The old JDRF research application form or the NIH form 398 is no longer be accepted by JDRF. proposalCENTRAL™ is JDRF's web- based grant management service provider. You can register and apply using the following URL: https://v2.ramscompany.com/Login.asp : (**CLICK HERE** for instructions)

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

NOTE: If you are a JDRF Reviewer with a pre-existing registration as a Reviewer, please use the same login information to apply for a grant.

NOTE 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.

GENERAL INFORMATION:

- Applications for funding from JDRF must have relevance to type 1 diabetes and one or more of the JDRF research emphasis areas.
- Please note that although they have similar titles, the templates for the various application types are different. Applicants should check that they are using the correct template for the type of grant they are applying for. These templates can be downloaded directly from the proposalCENTRAL™ website.
- Applications are accepted worldwide, and there are no citizenship requirements.
- JDRF grant awards limit indirect costs to a maximum of 10% of direct costs (excluding equipment), and no exceptions will be granted. There are no indirect costs allowed for Fellowship Awards.

GENERAL REVIEW PROCESS:

- Generally, applications will undergo a pre-review process. Applications not recommended for full review will not receive brief written critiques. 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.
- All grant applications are subject to scientific peer review by the JDRF Medical Science Review Committee and by the Lay Review Committee, with final approval determined by the International Board of Directors. These groups evaluate the scientific merit of each application; the qualifications, experience, and productivity of the investigator; the facilities available; and the relationship of the research to the cause, cure, treatment, and/or prevention of diabetes mellitus and its complications.

FUNDING:

- Applicants will be notified in writing within (4) weeks of the review date regarding the final status of their applications. Status of an application will not be given by phone.
- Acknowledgement of support from the "Juvenile Diabetes Research Foundation International (JDRF)" must be made in any publicity given to the research and in all research publications, abstracts, and presentations arising, in whole or in part, from funds provided by JDRF awards.
- Funds for awards will not be released until appropriate ethical approval for human and/or animal studies is received.
- Recipients may not transfer awards between institutions without prior written approval from JDRF. Budget revision in excess of 20% of the total direct costs for all regular research grants, innovative grants, and training grants requires prior written approval from JDRF. Budget revision in excess of 10% of the total direct costs for all center grants, program project grants, industry grants, and clinical investigations grants also requires prior written approval from JDRF. Please see JDRF website for further information regarding Budget Guidelines.

APPLICATION CONTENT:

- **IMPORTANT: File Size Limit:** Most foundations limit the size of the files they will accept. The purpose for limiting file size, as well as page limits, is to facilitate review of the application. Very large files can make a full and comprehensive review of the application extremely difficult as our review panel members must download your PDF uploads. Therefore, **Proposal Narrative uploaded PDF files can be no larger than 20 MB**. The objective is to find a balance between the content of your application and file size. MS Word and the PDF generators provide tools that enable you to reduce the size of your files (see sections below for tips)
- Applications must be clear, readily legible, and in English; the type size must be 10 point or greater with no more than six lines of type per vertical inch. If the typeface is reduced in size, the application will be returned without review.
- Margins, in all directions, must be at least ½ inch.
- The applicant must include a complete mailing, phone, fax, and e-mail address.
- Funding requests must be submitted in U.S. dollars.

- Please note that in addition to the electronic application being submitted by the deadline date, (1) hard copy of the original of the complete application form must be received by JDRF within ONE week of the deadline date.
- The application must include (2) abstracts: one written for scientific audience and one for lay audience.
- 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.
- Applicants must 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.
- The reviewers of your JDRF application will NOT have access to the hard copies of the application. Thus, **ALL** required information must be submitted on-line. Failure to submit ALL required documents on-line will result in administrative triage of your application.
- Failure to submit a budget, biosketches or any other part of the application will result in an automatic administrative triage.
- The Proposal Narrative for ALL applications must be submitted on the current JDRF Proposal Narrative Template provided on the proposalCENTRAL Web site. Proposal Narratives submitted on forms other than the current template will be administratively triaged.

CLINICAL STUDIES:

- All applications to the Clinical Investigations Study Section, regardless of grant mechanism, must follow the Guidelines for Clinical Investigations Research and must include a Human Research Subject Plan. Clinical applications without such a plan will be administratively triaged.
- Applications proposing research with human subjects must be submitted to the Clinical Investigations Study Section, with the exception of studies using only human tissue (i.e. cell lines, blood, urine, etc.) without **ongoing** patient contact.
- All applicants proposing human embryonic stem cell research must read the JDRF Policy Statement/Guidelines for the use of Human Embryos in Stem Cell Research (**CLICK HERE**). Applicants proposing the use of human fetal tissue must read the JDRF Policy Statement/Guidelines for the use of Human Fetal Tissue in Research. (**CLICK HERE!**)
- All Innovative grant applicants that propose clinical trials or other 'hands on' patient-oriented research must adhere to the twice yearly application deadlines posted for Regular Research Grants, and Training Awards. They must also follow the JDRF guidelines for Clinical Investigations Research Proposals. If you have questions about which deadline is appropriate for your Innovative Grant proposal, please contact a member of the Research Staff.

RESUBMISSIONS:

- All resubmitted applications must include:
  - -A copy of the summary statement for the original application and
  - -A rebuttal letter (limited to two pages) addressing each of the reviewers' concerns

These documents should be included in the "Resubmission" section of the research plan. Applicants that have not received an electronic copy of their summary statement should contact JDRF.

COMPLETING AN ELECTRONIC APPLICATION:

1. Fill out each of the proposal sections listed in the table of the left hand side of the screen including Title Page, Applicant/PI, Institution and Contacts, Key Personnel, Abstract, and Organization Assurances (applicants do not need to fill out the signature page as information is automatically transferred to this page). When satisfied with all of the information within a section, press next to save any changes and proceed to the next section.

2. Click on the "Proposal Narrative and Other Attachments" link and download the Proposal Narrative Template. Please note that the Proposal Narrative must contain the following sections: Table of Contents, Budget, Biosketches, Research Plan, and Supporting Documents. Once completed, this form should be paginated and saved as a pdf file. To upload, select Proposal Narrative as the attachment type and browse your computer to insert the Proposal Narrative file. Finally, click the upload attachment button to complete the process.

Please consider the following recommendations when completing the Proposal Narrative:

- Limit the file size of the Proposal Narrative to 3-4MB
- Do not use text boxes
- When incorporating figures into the text follow these steps:
- Complete and save the text version of your document as a MS Word file.
  1. Save your figures as individual **JPG** files. Make sure the figures are saved as straight graphics and are NOT part of a text box.
  2. Select "Insert -> Picture -> From File" from the menu in MS Word. Select the JPG file you want to insert, and click on the "Insert" button.
  3. Wrap the text around the inserted figures.
- In order to adjust the page numbering follow these steps:
  1. Select "View->Header and Footer" from the menu in MS Word.
  2. Click on the "Format Page Number" (the fourth icon from the left on the Header and Footer bar) under the Header and Footer menu
  3. Click on "Start at" under Page Numbering and choose the page number for the table of contents page. Click on the "OK" button.
- Do NOT include your social security number or passport number in this application.

3. Print a hard copy of the application directly from the proposalCENTRAL Web site, by using the print function, for the following sections of the application. PLEASE NOTE: THE FOLLOWING ARE THE ONLY SECTIONS OF THE APPLICATION THAT SHOULD BE PRINTED (the title page, applicant/PI, and institution and contacts section do not need to be printed as this information is already included in the signature page section):

   - Signature Page
   - Key Personnel
   - Abstract
   - Organization Assurances
   - Proposal Narrative

4. Assemble the hard copy of the application using these sections in the order listed above.

5. Obtain appropriate signatures. The Signature Page must be signed by:
   i) The principal investigator,
   ii) *Sponsor (*Post Doc Fellows and Early Career Patient-Oriented Diabetes Research Award applicants ONLY*)
   iii) **Department Head (*Advanced Post Doc Fellows and Career Development Award applicants ONLY*)
   iv) The administrative officer, and
   v) The official with fiscal responsibility.

6. Make (1) copy original and mail to JDRF. See Contacts section.

7. To complete the online submission, press the "Submit Proposal" button. Please note only applications that are submitted to proposalCENTRAL will be accepted for review. Failure to press the submit proposal button, will result in automatic administrative triage of your application.

GENERAL TIPS WHEN USING PROPOSALCENTRAL™:

USING TEMPLATES:

The Proposal Narrative and Other 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 your word processing software, e.g., MS Word, to complete the template, then convert your file to PDF and return the completed attachment file to your online application.
Some of the files you download will be *'required'* attachments. All the required attachments are listed in the section directly above the templates section. This display is merely a tool to help you keep track of your completed *required* files. Once you upload a completed 'required' template, the template name will display in the 'Current list of uploaded attachments.'
The 'Validate' link, located in the gray navigation menu and available from every online page of the online application will also serve as a tool to check that at least one of each of the *required* attachment types is attached in your application.

LANGUAGE AND FORMATTING TEXT

- Always include applicant's name in the left-hand corner of each page (in the MS Word template, it is located in the "header" and will carry forward to subsequent pages).
- Use English only and avoid jargon and any unusual abbreviations.
- Page limitation and format requirements must be followed in completing the template.
- Type size limitations must be observed throughout the application. Use **10-point font** size only
- Be consistent with the use of font styles and indentation.
- Figures, charts, tables, figure legends, and footnotes may be smaller in size but they must be clear and legible.
- It is important that applicants correct any changes to templates resulting from input of data. Data should be completed in the space provided. Each template page must respect the original margins on all sides.
- Failure to follow format requirements may result in disqualification.

IMAGES IN DOCUMENTS

- **IMPORTANT: File Size Limit:** Most foundations limit the size of the files they will accept. The purpose for limiting file size, as well as page limits, is to facilitate review of the application. Very large files can make a full and comprehensive review of the application extremely difficult as many of our review panel members must download your PDF uploads. Therefore, **Proposal Narrative upload PDF files can be no larger than 20 MB**. The objective is to find a balance between the content of your application and file size. MS Word and the PDF generators provide tools that enable you to reduce the size of your files (see sections below for tips)
- Research Plan page limits do NOT include figures, charts and tables.
- Reduce the file size of documents with images by "inserting" the image (as opposed to "cutting" and "pasting"). Save graphical images as a .jpg or .gif file. Insert the image into the document by selecting "Insert – Picture – From File" from the MS Word menu.
- Insert only .GIF or .JPG graphic files as images in your Word document (other graphical file formats are either very large or difficult to manipulate in the document).
- Do not insert Quick Time or TIFF objects into your document.
- Anchor the images that you embed in your document.
- Once you have anchored the "inserted" image, you can format text to wrap around the image.

- Do not edit your images in Word. Use a graphics program.
- Do not embed your images in tables, text boxes, and other form elements.
- Do not add annotations over the images in Word. Add annotations to the images itself in a graphics program.

OTHER TIPS AND TECHNIQUES FOR TEMPLATES

- For some templates, e.g., "Biosketch," a single biosketch template is provided for you to complete. For projects with multiple key personnel, you can create a single document with biosketches of all the key personnel by copying the template provided and pasting copies one after the other for as many people as required. Follow the guidelines provided by the sponsor.
- Do not use 3rd party programs for references. Use the available reference tools built into MS Word.

CONVERTING A TEMPLATE TO A PDF FILE

- **IMPORTANT: File Size Limit:** Most foundations limit the size of the files they will accept. The purpose for limiting file size, as well as page limits, is to facilitate review of the application. Very large files can make a full and comprehensive review of the application extremely difficult as many of our review panel members must download your PDF uploads. Therefore, **Proposal Narrative upload PDF files can be no larger than 20 MB**. The objective is to find a balance between the content of your application and file size.
- To save your documents as PDFs, you will need to use PDF generator software. The National Endowment for Humanities website (neh.gov) provides a sampling of PDF generators, available for both PCs and Macs, along with websites that will do the conversion for you. Many are free or very low-cost. Use the following URL for a list of PDF generators: http://www.neh.gov/grants/grantsgov/pdf.html.

CONVERTING A FILE TO PDF:

- **IMPORTANT: File Size Limit:** Most foundations limit the size of the files they will accept. The purpose for limiting file size, as well as page limits, is to facilitate review of the application. Very large files can make a full and comprehensive review of the application extremely difficult as many of our review panel members must download your PDF uploads. Therefore, **Proposal Narrative upload PDF files can be no larger than 20 MB**. The objective is to find a balance between the content of your application and file size.
- There are various ways to proceed through the steps for converting a template to pdf format. These can change depending on how the software was installed on your computer. The most universal method is to:
- open the MS Word document
- select "File – Print" from the menu - *a "Print" dialog box will appear.*
- click on the drop down list arrow for the printer "Name" field - *a list of printers will appear*
- select "Acrobat Distiller"
- click on "Ok" - *a "Save PDF File As" dialog box appears*
- type in a name for the PDF file. ***Note**: Ensure the file name has no extraneous characters e.g., no spaces, brackets, hyphens, underscores, commas, quotes etc.*
- click "Save"
- *The conversion will begin. When the process is complete the pdf file will open in an Adobe Acrobat window, ready for you to view.*

UPLOADING YOUR (COMPLETED) TEMPLATE BACK TO YOUR ONLINE APPLICATION:

Once you have converted your application template to a PDF file, the next step is to upload the file to your online application.

- make certain that the converted PDF file is closed on your computer
- open your application and go to the page from which you downloaded the template
- enter your own description of the file in the "Describe Attachment" field
- choose from the drop-down list of attachment types, e.g., Biosketch, Other Support
- click on the "Browse" button - *a 'choose file' dialog box opens for you to search for the template file on your computer's hard disk/network*
- select the file and click "Open" - *the file location and name will display in the window adjacent to the Browse button*
- click on the "Upload Attachment" button

The file is now attached to the application. You will also see that your file is now listed in the Uploaded Attachment section (directly below the Upload Attachment button). Two links are available in each row of an uploaded attachment: DEL 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*** word processing document **(offline),** convert the file to PDF and once again, 'attach' the newly revised file. **Delete any previously submitted versions of the file.**

SUBMITTING THE ELECTRONIC APPLICATION & PRINTING THE SIGNATURE PAGES:

- Click on the 'Validate' link, located in the gray navigation menu and accessible from any of the online pages. 'Validate' checks for missing required entries on all pages of the application, and any missing attachments.
- After you complete all the proposal sections, click the (red) Print Signature Pages button. Clicking the print button will open the cover/signature pages in PDF format. Data that you entered in the other sections of the proposal are automatically included in the cover/signature pages. If information is missing in the cover/signature pages, it could be because you have

not entered the information in one of the proposal sections OR the information is not required for this grant program. ***REMINDER: Before printing, please use the 'Validate' option (in the gray navigation menu to the left) to verify that you have entered all the required information.***

- Additionally, you may click on the 'Print Signature Pages and Attached PDF Files.' Click this button to print the signature pages plus attached PDF files. (Excludes non-PDF files.)

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PROPOSALCENTRAL CONTACTS:

support@ramscompany.com
(301)-916-4557 ext. 227, or toll free in the US, (800)-875-2562 ext. 227
Assistance can be obtained Monday through Friday between 8:30am and 5pm U.S. Eastern Time.

DEADLINES:

REGULAR RESEARCH GRANTS AND TRAINING AWARDS

JDRF accepts applications for the following award types (2) times a year:

- Regular research grant
- Career development award
- Early career patient-oriented diabetes research award
- Advanced postdoctoral fellowship
- Postdoctoral fellowship
- Innovative Grant (only those that propose clinical trials or other 'hands on' patient-oriented research)

Online Application deadline*	Original Hardcopy Application deadline*	Review date	Notification**	Earliest Funding start date
July 14, 2006	July 21, 2006	November 2006	December 2006	February 1, 2007
January 15, 2007	January 22, 2007	May 2007	June 2007	August 1, 2007

*Electronic submission of applications is required. Please note that (1) signed, original hardcopy must also be submitted and received by the JDRF.

**Applicants will be notified by mail or e-mail only. Results will not be given out by telephone.

INNOVATIVE GRANTS

JDRF accepts applications for this award type (3) times a year.

Online Application deadline*	Original Hardcopy Application deadline*	Review date	Notification**	Earliest Funding start date
July 14, 2006	July 21, 2006	September 2006	October 2006	December 1, 2006
November 17,2006	November 24, 2006	January 2007	February 2007	April 1, 2007
March 16, 2007	March 23, 2007	May 2007	June 2007	August 1, 2007

*Electronic submission of applications is required. Please note that (1) signed, original hardcopy must also be submitted and received by the JDRF.

**Applicants will be notified by mail or e-mail only. Results will not be given out by telephone.

NOTE: All applicants that propose clinical trials or other 'hands on' patient-oriented research must adhere to the twice yearly application deadlines posted for *Regular Research Grants, and Training Awards*. They must also follow the JDRF guidelines for Clinical Investigations Research Proposals. If you have questions about which deadline is appropriate for your Innovative Grant proposal, please contact a member of the Grants Staff.

PROGRAM PROJECT & CLINICAL INVESTIGATION RESEARCH GRANTS

LOI Deadline	Online Application deadline*	Original Hardcopy Application deadline*	Review date	Notification**	Earliest Funding start date
06/30/06	09/15/06	09/22/06	11/06	12/06	02/01/07
01/02/07	03/16/07	03/23/07	05/07	06/07	08/01/07

NOTE: A letter of intent (LOI) must be approved prior to submission of an application for a program project grant, and clinical investigations research grant. Please see Grant Award Mechanisms for further details. Once approved via the LOI process, JDRF accepts full applications for these award types twice a year. Please contact JDRF Staff before submitting LOIs.

INDUSTRY DISCOVERY & DEVELOPMENT PARTNERSHIPS

Industry Discovery & Development Partnerships (IDDP) LOIs and applications are reviewed on a rolling basis. See IDDP page for full details.

JDRF CENTER APPLICATIONS

NOTE: Letters of intent (LOI) must be approved prior to submission of a Center application. Please refer to the following table for deadlines for receipt of LOIs and full applications. Further details about the LOI process is provided in the RFA for Grant Mechanisms. Note that deadlines differ by research topics.

Topic	LOI deadline	LOI decision	Application deadline	Review date	Funding start date
Complications	3/1/06	3/31/06	7/15/06	10/1/06	2/1/07
Autoimmunity and Prevention	2/1/07	3/1/07	6/1/07	10/1/07	2/1/08
Human Islet Transplantation	8/1/07	9/1/07	12/1/07	4/1/08	8/1/08

Notification of Awards:
Applicants will be notified in writing within (4) weeks of the review date regarding the status of their applications.

ALL ORIGINAL HARDCOPY APPLICATIONS MUST BE MAILED TO THE FOLLOWING ADDRESS:

Juvenile Diabetes Research Foundation International
Attention: Grant Staff
120 Wall Street, 19th Floor
New York, NY 10005-4001, USA.

1.0 Regular Research Grant

DESCRIPTION: NOTE: IF YOUR PROJECT INVOLVES CLINICAL STUDIES, CLICK HERE

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 the 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 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 the Industry Discovery & Development Partnerships section for information on JDRF funding programs for industry and how to apply.

MECHANISMS OF SUPPORT:

JDRF Regular Research Grants will be supported for a maximum of $165,000 total costs per year for a period 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 or other funding is not available) support beyond 3 years will be considered based on a competitive review of the accomplishments and future plans.

PROPOSAL NARRATIVE:

The Proposal Narrative of the application must be completed using the template provided on the proposalCENTRAL Web site. The Proposal Narrative must contain the following sections: Table of Contents, Budget, Biosketches for all listed key personnel, Research Plan and Supporting Documents.

RESEARCH PLAN:

The research plan may not exceed 10 pages not including figures and tables. Please note that the 10-page limit includes narrative items *a* through *d* as described below. **Applications with research plans exceeding the page limit will not be reviewed.** The narrative sections should be typewritten, single-spaced, and in typeface no smaller than **10-point font**. Margins, in all directions, must be at least ½ inch. Complete information should be included to permit review of each application without reference to previous applications. The research plan must be organized as follows: A) Specific Aims; B) Background and Significance of this work to Type 1 Diabetes; C) Preliminary Studies/Progress Report (for competitive renewal); D) Research Design and Methods; E) Literature Cited (no page limit); F) Principal Investigator Assurance. All information in items A through D must be incorporated in the 10-page limit without exception.

REVIEW CONSIDERATIONS:

Applications will be evaluated in accordance with the criteria described below. Evaluations will be competitive and performed by an appropriate peer and lay review group convened by the JDRF. The review criteria will include:

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

EVALUATION:

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.

2.0 Innovative Grant

DESCRIPTION: NOTE: IF YOUR PROJECT INVOLVES CLINICAL STUDIES, CLICK HERE

JDRF supports highly innovative basic and clinical research that is at the developmental stage by providing "seed" money for investigative work based on sound scientific hypotheses for which preliminary data are insufficient for a regular research grant but that are likely to lead to important results for the treatment of diabetes and its complications. These grants provide one year of support for a maximum of $100,000 in direct costs and indirect costs of 10%, for a total of $110,000. These grants are not renewable.

These grants will be evaluated on the following criteria:

- Is the proposed research innovative?
- Is the underlining premise, goal or hypothesis plausible?
- Can the proposed research be completed in one year?
- Is the proposed research relevant to the mission of JDRF and what is its potential impact?

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.

PROPOSAL NARRATIVE:

The Proposal Narrative of the application must be completed using the template provided on the proposalCentral web site. The Proposal Narrative must contain the following sections: Table of Contents, Budget, and Biosketches for all listed key personnel, Research Plan and Supporting Documents.

RESEARCH PLAN:

The innovative grant research plan may not exceed 3 pages and preliminary studies are not required. Please note that the 3-page limit includes narrative items A through D as described below. Applications with research plans exceeding the page limit will not be reviewed**.** The narrative sections should be typewritten, single-spaced, and in typeface no smaller than 6 lines per vertical inch, 10-point font. Margins, in all directions, must be at least ½ inch. Complete information should be included to permit review of each application without reference to previous applications. 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 available); D) Research Design and Methods; E) Literature Cited (no page limit); F) Principal Investigator Assurance.

3.0 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.

NOTE:

- In general, complimentary registration for a designated member of JDRF staff, or JDRF guests, is required for JDRF sponsorship of a meeting. JDRF sponsorship must be acknowledged in all publicity and in the program for the meeting and any proceedings or publications resulting from the meeting.
- Copies of proceedings or publications resulting from the meeting must be provided to JDRF.
- 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 applicant is required to provide a brief report, written in lay terms, after the meeting for posting on the JDRF website.

ELIGIBILITY:

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

- How does the meeting relate to JDRF goals?
- Need and timeliness of the meeting
- Format and agenda
- Qualifications of the organizers and proposed participants
- Past performance of the meeting, when applicable
- Appropriateness of the meeting site
- Appropriateness of the budget

APPLICATION:

Conference Grant applications are accepted for consideration throughout the year. Applicants will be notified in writing within (1) 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 below. The JDRF review panel may request supplemental information. Letters of intent and accompanying documents should be sent to:

Sasha Del Valle
Juvenile Diabetes Research Foundation
120 Wall Street- 19th Floor
New York, NY 10005, USA

sdelvalle@jdrf.org

Requests of $10,000 or more

A formal JDRF application must be submitted by a representative of the applicant organization. Mail (10) copies of the completed application to:

Sasha Del Valle
Juvenile Diabetes Research Foundation
120 Wall Street- 19th Floor
New York, NY 10005, USA

sdelvalle@jdrf.org

JDRF Application for Funding of Conferences and Workshops

Title of Conference:			
Name (Last, First, Middle):			
Position Title:			
Institution:		**Department:**	
Mailing Address:			
Tel:		**Fax:**	
E-mail Address:			
Dates of Meeting:		**Location of Meeting:**	
Amount Requested:	$		
Applicant Organization:			
Address of Applicant Organization:			

Administrative Official to be notified if Award Is Made:

Name:			
Title:			
Address:			
Tel:		**Fax:**	
E-mail Address:			

The following items MUST be provided:

- **Scientific Abstract**
  Provide a scientific abstract for the conference (not to exceed one page).
- **Lay Abstract**
  Provide a lay abstract that explains the scientific abstract to persons with a nontechnical background (not to exceed one page).
- **Meeting Organizers**
  Provide a list of the meeting organizers followed by a biographical sketch of each (limited to three pages for each biographical sketch).
- **Budget**
  Provide a budget for the conference, including a breakdown of which agencies will be asked to contribute as well as how much they will be asked to contribute. Justify the budget in detail and explain the request for JDRF funds.
- **Dissemination of Information**
  Explain how the conference will be announced and what publications, if any, will result.
- **Conference Speakers**
  List the speakers, their titles, and their affiliations.
- **Conference Program**
  Provide the proposed program for the meeting.
- **JDRF Criteria**
  Explain how the conference meets JDRF funding criteria (see Instructions to Applicants). Do not exceed five pages.

Certification: We the undersigned certify the information submitted is accurate and complete to the best of our knowledge and accept the terms and conditions of JDRF, in effect, if this application is funded.

Signatures: Applicant_____

Responsible Administrative Official_____

4.1 Postdoctoral Fellowships

DESCRIPTION: NOTE: IF YOUR PROJECT INVOLVES CLINICAL STUDIES, CLICK HERE

These 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 (Ph.D., M.D., D.M.D., D.V.M.) 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 (M.D., Ph.D., D.M.D., D.V.M., 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 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.

INSTRUCTION:

Please note that in addition to the electronic application being submitted by the deadline date, a hard copy of the original plus two copies of the complete application form must be received by JDRF within ONE week of the deadline date.

PROPOSAL NARRATIVE:

The Proposal Narrative of the application must be completed using the template provided on the proposalCentral web site. The Proposal Narrative must contain the following sections: Table of Contents, Budget, Biosketches, Research Plan and Supporting Documents.

RESEARCH PLAN:

The research plan should be suitable for a two-year postdoctoral training period. The project should ask a specific and substantive question and be relevant to JDRF's mission. Extensive discussion between

the applicant and the proposed mentor is expected in order to identify an appropriate research project—one that is up-to-date, instructive, and suited to a two-year fellowship period.

The postdoctoral fellowship research plan may not exceed 7 pages not including figures and tables. Please note that the 7-page limit includes narrative items *a* through *d* as described below. **Applications with research plans exceeding the page limit will not be reviewed.** The narrative sections should be typewritten, single-spaced, and in type face no smaller than **10-point font**, and have no more than six vertical lines per vertical inch. Margins, in all directions, must be at least ½ inch. Complete information should be included to permit review of each application without reference to previous applications. 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 immediate area. Explain why you have chosen this problem. **C**) Preliminary Results (if available). **D**) Research Design 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 professionals with expertise in diabetes, participation in staff conferences, teaching, consultation, etc. **F**) List any planned course work. All information items A through D must be incorporated in the 7-page limit without exception. **G**) List pertinent literature references (no page limit). In addition, a Future Career Plans statement and a Training Plans statement must be included at the end of the Research Plan section.

SPONSOR:

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

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.

RECOMMENTATION REFERENCES:

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

EVALUATION:

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

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

TERMS OF AWARD & STIPENDS:

Awards are for two years, assuming satisfactory progress. The fellowship term is 12 months for each fellowship year, and fellows must devote at least 80% of their effort to the project outlined in the fellowship application. Recipients of the JDRF postdoctoral fellowship award cannot hold another postdoctoral fellowship at the same time.

Award amounts are based on years of relevant postdoctoral experience effective March 1, 2006. There are no indirect costs allowed for fellowships and JDRF will make no deductions for income tax, Social Security, etc. A research allowance of $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 $2000/year), journal subscriptions, books, training courses etc. They are not to be used for laboratory supplies or equipment. Personal computer costs are allowed. Health insurance costs are permissible. The award is renewable for a second year pending submission and approval of a renewal application and progress report.

Years	Stipend	Research Allowance	Total
0	**$36,996**	**$5,500**	$42,496
1	**$38,976**	**$5,500**	$44,476
2	**$41,796**	**$5,500**	$47,296
3	**$43,428**	**$5,500**	$48,928
4	**$45,048**	**$5,500**	$50,548
5+	**$46,992**	**$5,500**	$52,492

4.2 Advanced Postdoctoral Fellowships

DESCRIPTION: NOTE: IF YOUR PROJECT INVOLVES CLINICAL STUDIES, CLICK HERE

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 (Ph.D., M.D., D.M.D., D.V.M.) 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. Generally, their first degree (M.D., Ph.D., D.M.D., D.V.M., 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, so 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 women and members of minority groups underrepresented in the sciences.

Awards will be made to applicants who have demonstrated superior scholarship and show the greatest promise for future achievement in diabetes research, including either basic or clinically-relevant research.

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 NARRATIVE:

The Proposal Narrative of the application must be completed using the template provided on the proposalCentral web site. The Proposal Narrative must contain the following sections: Table of Contents, Budget, Biosketches for all listed key personnel, Research Plan and Supporting Documents.

RESEARCH PLAN:

The research plan should be suitable for a 3-year postdoctoral training period. The project should ask a specific and substantive question and be relevant to the JDRF 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 3-year fellowship period.

The postdoctoral fellowship research plan may not exceed 7 pages not including figures and tables. Please note that the 7-page limit includes narrative items A through D as described below. Applications with research plans exceeding the page limit will not be reviewed. The narrative sections should be typewritten, single-spaced, and in typeface no smaller than 10-point font, and have no more than six lines per vertical inch. Completed information should be included to permit review of each application without reference to previous applications. The review panels will consider the information provided as an example of the applicant's approach to a research objective and as an indication of his/her ability in this area of research.

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 immediate area. Explain why you have chosen this problem. C) Preliminary Results (if available). D) Research Design 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 professionals with expertise in diabetes, participation in staff conferences, teaching, consultation, etc. F) List any planned course work. G) List pertinent literature references (two-page limit). All information items A through D must be incorporated in the 7-page limit without exception. In addition, a Future Career Plans statement as well as Training Plans must be included at the end of the Research Plan section.

SPONSOR:

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

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.

RECOMMENTATION REFERENCES:

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

EVALUATION:

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

TERMS OF AWARD & STIPENDS:

Awards will be made for a duration of up to 3 years, assuming satisfactory progress. The fellowship term is 12 months for each fellowship year, and fellows must devote at least 80 percent of their effort to the project outlined in the application.

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

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

Years of Experience	Stipend
0	$35,568
1	$37,476
2	$41,796
3	$43,428
4	$45,048
5	$46,992
6	$48,852
7+	$51,036

TRANSITION AWARD:

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

4.3 Career Development Awards

DESCRIPTION: NOTE: IF YOUR PROJECT INVOLVES CLINICAL STUDIES, CLICK HERE

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 mission goals.

In the five-year term awardees will focus their research efforts in 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. The award is up to $150,000 per year, including indirect costs. These funds may be used for research allowance, which can include a technician, supplies, equipment and travel up to $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 details.

ELIGIBILITY:

The Career Development Award is intended for individuals in a relatively early stage of their career. Ordinarily, their first degree (M.D., Ph.D., D.M.D., D.V.M., 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 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 NARRATIVE:

The Proposal Narrative of the application must be completed using the template provided on the proposalCentral web site. The Proposal Narrative must contain the following sections: Table of Contents, Budget, Biosketches for all listed key personnel, Research Plan and Supporting Documents.

RESEARCH PLAN:

The Career Development Award research plan should describe a five-year project. The project should address a specific and substantive question that is relevant to the JDRF mission. The research plan may not exceed 10 pages not including figures and tables. Please note that the 10-page limit includes

narrative items a through d as described below. Applications with research plans exceeding the page limit will not be reviewed.
The narrative sections should be typewritten, single-spaced, and in typeface no smaller than 10-point font. Margins, in all directions, must be at least ½ inch. Complete information should be included to permit review of each application without reference to previous applications. The research plan must be organized as follows: A) Specific Aims; B) Background and Significance of this work to Type 1 Diabetes; C) Preliminary Studies (if applicable); D) Research Design and Methods; E) Literature Cited (no page limit). All information in items A through D must be incorporated in the 10-page limit without exception. In addition, a Future Career Plans statement must be included at the end of the Research Plan section.

RECOMMENTATION REFERENCES:

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

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. The Department Head Statement must be included in the Supporting Documents section of the Proposal Narrative.

EVALUATION:

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

TERMS OF AWARD:

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.

4.4 Early Career Patient-Oriented Diabetes Research Award

DESCRIPTION: NOTE: IF YOUR PROJECT INVOLVES CLINICAL STUDIES, CLICK HERE

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 M.D. or M.D.-Ph.D., hold an appointment or joint appointment in a subspecialty of clinical medicine, and conduct human clinical research. In exceptional circumstances, non-M.D. 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 an 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 women and members of minority groups underrepresented in the clinical 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 NARRATIVE:

The Proposal Narrative of the application must be completed using the template provided on the proposalCentral web site. The Proposal Narrative must contain the following sections: Table of Contents, Budget, Biosketches for all listed key personnel, Research Plan and Supporting Documents.

RESEARCH PLAN:

The early career patient-oriented research plan may not exceed 10 pages not including figures and tables. Please note that the 10-page limit includes narrative items a through d as described below. Applications with research plans exceeding the page limit will not be reviewed. The narrative sections should be typewritten, single-spaced, and in typeface no smaller than 10-point font. Margins, in all

directions, must be at least ½ inch. Complete information should be included to permit review of each application without reference to previous applications. 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 items A through D must be incorporated in the 10-page limit without exception.

In addition, a Future Career Plans statement and a Training Plans statement must be included at the end of the Research Plan section. These sections should detail the applicant's plan for career development as an independent investigator as well as the plans of the mentor/institution for supporting that development. 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. The mentor's statement should address plans for supervision, guidance, counseling, or other formal or informal training of the applicant.

SPONSOR:

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

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.

RECOMMENTATION REFERENCES:

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

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. The Department Head Statement must be included in the Supporting Documents section of the Proposal Narrative.

EVALUATION:

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

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

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

Indirect costs (excluding equipment) cannot exceed 10%. Please see JDRF’s budget guidelines for details.

5.0 Program Project Grants

NOTE:

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

DESCRIPTION: NOTE: IF YOUR PROJECT INVOLVES CLINICAL STUDIES, CLICK HERE

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

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

ELIGIBILITY:

Applicants must hold an 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, 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 description of special program for for-profit entities. There are no citizenship requirements and racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators.

LETTER OF INTENT:

A letter of intent is required. Prospective applicants should submit a letter of intent on-line via the proposalCENTRAL Web site https://v2.ramscompany.com/login.asp . The LOI template provided on the proposalCENTRAL Web site must be used to complete the application.

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

In addition to the electronic LOI submission, applicants should send the original signed letter of intent to:
Grant Manager, Juvenile Diabetes Research Foundation International
Attention: Letter of Intent, 120 Wall Street, 19th Floor, New York, NY 10005- 4001 USA

APPLICATION:

The Program Project proposal should contain the following: Administrative Information about the Program Project, a Table of Contents, Program Project overview and individual projects. Program Projects can consist of 3 to 6 individual projects and 1 to 3 core services.

1. Administrative Information about the Program Project — Complete the following forms for the Program Project as a whole (applicants do not need to fill out the signature page as information is automatically transferred to this page):
    a. Title Page
    b. Applicant/Program Director
    c. Institution and Contacts
    d. Key Personnel
    e. Abstract
    g. Organization Assurances

2. Table of Contents — Prepare a detailed table of contents that will enable reviewers to find specific information readily. Use the table of contents template provided as part of the Program Project Overview. Organize the table of contents so that the Program Project Overview and each individual project and core are listed as headings in the table of contents.
   Identify each project by title, and assign each project a number and each core unit a capital letter, and provide the name of the investigator responsible for each component. Number the pages consecutively.

3. Program Project Overview — includes a description of the overall goals of the Program Project and each individual project, the relationship of the projects to each other and the Program Project and a composite budget for the entire Program Project. The Program Project Overview should not exceed 15 pages.

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

BUDGET:

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

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

ORGANIZATION:

(the title page, applicant/program director, and institution and contacts section do not need to be printed as this information is already included in the signature page section)
Signature Page
Key Personnel

Abstract
Organization Assurances
Table of Contents
Program Project Overview (maximum 15 pages excluding tables, figures and references)
- Summary Statement from Original application (for revised applications only)
- Introduction to Program Project — description of overall goals of the Program Project, individual projects and Cores
- Composite Budget for initial budget period for entire Program Project
- Composite Contractual Costs for initial budget period for entire Program Project
- Composite Budget for entire period for whole Program Project
- Other Support including Abstract Pages from all other sources of support (current and pending)
- Resources
- Program Director's Biographical Sketch

For each individual project and/or core
- Face Page
- Program Focus and Key Personnel
- Scientific and Lay Abstracts
- Table of Contents
- Budget
- Biographical sketches
- Research Plan/Core Description (maximum 10 pages), tables, figures and references
- Supporting Documents

Please send one original application, plus 2 copies (total 3) of the complete application, supporting documents and letters. Please send the application to:

Grant Administrator
Juvenile Diabetes Research Foundation International
120 Wall Street, 19th Floor, New York, NY 10005 USA

REVIEW CONSIDERATIONS:

Each Program Project application contains a Program Project overview and individual projects. The Program Project overview includes a description of the overall goals of the Program Project and each individual project, the relationship of the projects to each other and the Program Project, a description of the Cores (shared facilities used by most of the investigators in the Program Project), the budget requests for the Cores and a composite budget for the entire Program Project. Each individual project includes a research proposal, detailed budget requests, biographical sketches and information about other support for the applicants.

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

SCIENTIFIC REVIEW:

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

LAY REVIEW:

There will be Lay Review Committee (LRC) members present at the peer review meeting. Each of the lay reviewers will be assigned applications in a similar manner to the scientific review committee. In addition

to having reviewed applications prior to attending the meeting, they will listen to the deliberations and take the reviewers' commentary into consideration as part of the lay review. The LRC meeting will take place following the scientific review. All applications will be examined closely and those deemed inconsistent with the mission of the JDRF will be removed from further consideration. Those applications meeting both the scientific and JDRF criteria will be chosen for the funding recommendations made to the JDRF International Board of Directors.

JDRF BOARD REVIEW:

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

REVIEW CRITERIA OF INDIVIDUAL PROJECTS:

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

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

REVIEW OF THE PROGRAM PROJECT ASPECTS:

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

- Potential to develop and prove principle of new approaches to unsolved problems of Type 1 diabetes
- Relevance to the objectives of JDRF
- Scientific, technical, or medical significance of the Program Project
- Scientific merit of the Program Project as a whole, as well as that of the individual research projects
- Appropriateness and adequacy of the experimental approach and methodology
- Innovation
- Synergy
    - Will there be a team of investigators with various types of expertise undertaking collaborative multidisciplinary research in the health sciences in various institutions?

    - Will there be research components, each scientifically meritorious, which together form an integrated research program able to address issues which could not readily be approached were the components to be funded separately?
    - Evaluation of the cohesiveness of the Program Project and the coordination and interrelationships of individual projects and core(s) to the common theme. What are the relative priorities of the various projects, is there a chronological relationship, and should they all be included in the Program Project?
- Investigators
    - Assessment of the leadership and scientific ability of the principal investigator of the Program Project:
    - his or her ability to develop a program of integrated research projects with a well-defined central research focus;
    - and his/her commitment and ability to devote adequate time and effort to the program.
    - What is the role of each investigator as part of the Program Project: time commitment and who is going to do what?
    - Will each investigator be able to devote adequate time and effort to the program?
- Core facilities — Each core must provide essential facilities or services for two or more individual research projects. Review criteria for scientific cores consist of the following:
    - Justification and usefulness of the core facilities to the various research projects;
    - Relationship of each core to the central focus of the overall Program Project;
    - Quality of relevant facilities or services provided by the core (including procedures, techniques and quality control) and criteria for prioritization and usage;
    - Qualifications, competence and commitment of the Core leader and key personnel.
- Organization and Communication — Will the organizational aspects of the Program Project structure allow the proposed research to occur? Assessment of the plans for meetings, other interactions, and exchange of data, material and techniques. Comment on the geographical distribution of the Program Project members.
- Institutional and other sources of support — What is the institutional commitment to the Program Project and the impact of the Program Project on the institutions involved in terms of research priorities of the institution, financial support, time protection, and laboratory space and equipment? Are there any other sources of financial support for the request, which could include: cost-sharing arrangements with the sponsoring institution(s), industry (keeping in mind that university-industry collaborations are encouraged), or other agencies; estimates of institutional expenditures involved in upgrading or constructing laboratory facilities; estimates of indirect institutional support such as provision of services and computing resources; user fees.

EVALUATION:

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

TERMS OF AWARD:

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

6.0 Clinical Investigations Research Grant

NOTE:

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

NOTE:

- All applications to the Clinical Investigations Study Section, regardless of grant mechanism, must follow the Guidelines for Clinical Investigations Research and must include a Human Research Subject Plan. Clinical applications without such a plan will be administratively triaged.
- Applications proposing research with human subjects must be submitted to the Clinical Investigations Study Section, with the exception of studies using only human tissue (i.e. cell lines, blood, urine, etc.) without **ongoing** patient contact.
- All 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.

DESCRIPTION:

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

TERMS OF AWARD:

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

ELIGIBILITY:

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, company, or other research facility.
Applications may be submitted by domestic and foreign non-profit organizations, public and private, such as colleges, universities, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government that are accredited to perform clinical research.

Ordinarily, for-profit organizations will not be considered, except under special circumstances. See the Industry Discovery & Development Partnerships section for description of special program for for-profit entities. There are no citizenship requirements and racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators.

LETTER OF INTENT:

Prospective applicants should submit a letter of intent on-line via the proposalCENTRAL Web site (https://v2.ramscompany.com). The LOI template provided on the proposalCENTRAL Web site must be used to complete the application. A description of the Clinical Investigation should address clinical study design, plans for patient recruitment and informed consent, the potential benefits and information about the risks to patients, plans to minimize potential risks, and the likely effectiveness of such plans see Guidelines. For proposed clinical trials, the letter should also include a power calculation and a data safety monitoring plan. Research project descriptions should contain sufficient detail to allow JDRF to identify potential scientific reviewers to review the application.

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

In addition to the electronic LOI submission, applicants should send the original signed letter of intent to:
Michelle Cissell, Ph.D.
Scientific Program Manager
Juvenile Diabetes Research Foundation International
Attention: Letter of Intent
120 Wall Street, 19th Floor
New York, NY 10005-4001 USA

APPLICATION:

JDRF will no longer be accepting applications on the NIH PHS 398 application form. All Clinical Investigations Research Grant Applications must be submitted electronically via the proposalCentral web site, using the provided JDRF Proposal Narrative Template. The narrative section should be typewritten, single-spaced, and in type face no smaller than 10-point font.

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

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

RESEARCH PLAN:

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

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

Please note that in addition to the electronic application being submitted by the deadline date, one original application plus two copies (total 3) of the complete application form, supporting documents and letters must be received by JDRF by the deadline date. Please send the application to:

Grant Administrator
Juvenile Diabetes Research Foundation International
120 Wall Street, 19th Floor
New York, NY 10005, USA

GUIDELINES:

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

A. CLINICAL STUDY DESIGN

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

1. Summary of proposed study objectives and design: Briefly state the goal of the study, describe the study design, and justify its use. If alternative study designs are possible (for example, randomized placebo control, cross-over, open label, etc.), discuss the reasons for choosing the proposed design. Identify the planned outcome measures and surrogate markers.

2. Subject recruitment and enrollment: Explicitly state inclusion and exclusion criteria for persons with Type 1 diabetes, at risk for Type 1 diabetes, family members, and healthy control subjects. Justify why these are chosen and discuss effect on potential recruitment where appropriate. Briefly describe plans for the type (health and disease status) and numbers of patients and controls to be enrolled, planned randomization procedures, and plans for how and over what duration study subjects will be recruited.

3. Study evaluation and statistical analysis: Include a brief non-technical description of how study results will be evaluated to support or provide evidence against the study hypothesis, including statistical methods to be employed. Include a rationale for proposed sample sizes. (This will generally rely on the typical distribution of the primary outcome measure in the target population and on anticipated effects in the study.) For clinical trials, include a power calculation. If applicable, provide alternative sample size and study design if a Bayesian analysis approach was adopted.

B. HUMAN RESEARCH SUBJECT PLAN

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

1. Criteria for subject inclusion/exclusion:

Describe the proposed involvement of human research subjects, including patients and healthy control subjects, stating their anticipated number, age range, sex, ethnic/racial background, and health status. Identify the criteria for inclusion or exclusion of any subpopulation, including children and adolescents. Include consideration of the privacy rights of both former and current patients. For example, address how previous guarantees of confidentiality in clinical or research settings will be honored in the way potential subjects are contacted.

2. Potential benefits and risks to subjects, plans to minimize risks and knowledge to be gained from the study:
In narrative format, for each proposed intervention and for each proposed subject group address the following factors1:

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

Note potential risks to pregnant women and fetuses.

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

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

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

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

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

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

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

6. Research subject informed consent:
Consent plans: Describe plans for the process for obtaining subject informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. Recognize that consent is an interactive process and that a signed form is merely evidence that the interaction took place.

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

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

Guidelines for the informed consent document are provided in Appendix C .
Submission of the finalized patient information and consent forms and written IRB approval will be required prior to initiation of funding.

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

8. Investigator education in the protection of human research subjects:
Describe, for all key personnel, education on the protection of human research subjects.

9. Projects involving drugs or devices
State whether the proposed clinical investigation involves the use of any drugs or devices and whether the drug or device is approved for the intended application. If not approved for the intended application, please indicate:
IND# or IDE#
Phase of the clinical study
Who holds the IND for this drug?
Submission of the FDA-IND letter, where applicable, will be required prior to initiation of funding.

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

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

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

APPENDIX B - U.S. Department of Health and Human Services Regulations Title 45 Part 46 Subpart D requirements for the participation of children in research
Subpart D of the human subjects regulations establishes requirements for research participation of children based on defined categories of potential risk and benefit of the research. The categories of research based on assessment on potential risks and benefits:
(1) No greater than minimal risk, where minimal risk means "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily

encountered in daily life or during the performance of routine physical or psychological examinations or tests"
(2) Greater than minimal risk and presenting the prospect of a direct benefit to the child, in which the anticipated benefit justifies the risk and is at least as favorable as that of alternative approaches
(3) A minor increase over minimal risk with no prospect of a direct benefit to the subject, but likely to yield generalizable knowledge about the child's disorder or condition that is of vital importance for the understanding or amelioration of the disorder or condition AND the intervention or procedure presents experiences to the child that are reasonably commensurate with those in the child's actual or expected medical, dental, psychological, social, or educational situations.
(4) Any other research, including research that poses more than a minor increase over minimal risk (for research in the United States and subject to the regulations, requiring the approval of the Secretary of Health and Human Services following consultation with a panel of experts and following publication and public comment).

APPENDIX C

INFORMATION TO BE INCLUDED IN THE CONSENT DOCUMENT

Informed consent forms provide written documentation of an ongoing and interpersonal process.
Information to be included in consent forms is listed below.*
1. A statement that the study involves research; identification of the research sponsor(s), principal investigator(s), and institution(s) performing the research;
2. An explanation of the purpose of the research, an invitation to participate and explanation of why the subject was selected, and the expected duration of the subject's participation;
3. A description of procedures to be followed and identification of which procedures are investigational and which might be provided as standard care to the subject in another setting. Use of research methods such as randomization and placebo controls should be explained;
4. A description of any foreseeable risks or discomforts to the subject, an estimate of their probability and magnitude, and a description of what steps will be taken to minimize or prevent them; as well as acknowledgement of potentially foreseeable risks;
5. A description of any benefits to the subjects or to others that may reasonably be expected from the research, and an estimate of their likelihood;
6. A disclosure of any appropriate alternative procedures or courses of treatment that might be advantageous to the subject;
7. A statement, when applicable, that participation in the research may limit the subject's eligibility for participation in future research studies.
8. A statement describing to what extent records will be kept confidential, including examples of who may have access to research records such as hospital personnel, the FDA, the drug sponsors;
9. For research involving more than minimal risk, an explanation and description of any compensation and any medical treatments that are available if subjects are injured through participation; where further information can be obtained, and whom to contact in the event of a research-related injury;
10. An explanation of whom to contact for answers to questions about the research and the research subject's rights;
11. A statement disclosing the research sponsor(s).
12. A statement that research is voluntary and that refusal to participate or a decision to withdraw at any time will involve no penalty or loss of benefits to which the subject is otherwise entitled;

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

REVIEW CONSIDERATIONS:

SCIENTIFIC REVIEW:

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

- Potential to prove principle of new approaches to unsolved problems of type 1 diabetes;

- Relevance to the objectives of JDRF;
- Scientific, technical, or medical significance of the research proposal;
- Innovative quality of the proposed study;
- Soundness of the clinical study design;
- Availability of sufficient pre-clinical data to justify the proposed clinical study;
- Qualifications and research experience of the principal investigators and collaborators;
- Consideration of the potential benefits and risks to patients who will be involved in the research, plans to limit risks, and other ethical considerations;
- Availability of resources and facilities necessary for the study;
- Appropriateness of the proposed budget in relation to the proposed research.

LAY REVIEW:

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

JDRF BOARD REVIEW:

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

EVALUATION:

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.

Inquiries regarding intended applications proposing clinical investigations should be directed to:

Michelle Cissell, Ph.D.
mcissell@jdrf.org
212-479-7664

7.0 Center Grants

DESCRIPTION: **NOTE: IF YOUR PROJECT INVOLVES CLINICAL STUDIES, CLICK HERE**

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

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

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

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

Key Elements Distinguishing JDRF Centers and Program Projects		
Element	**Center**	**Program Project**
Director	- Established diabetes investigator - Milestone-based management - Can add or delete projects - Re-budgeting authority	Milestone based management
Goals	Long Term	2 to 3 years
Approaches	Diverse	Interactive
Projects	- No upper limit - Enter and leave - “Catalyst” Alternative	- 3 to 6 - Define program
Administrative Core	Yes	When justified
Clinical Outcome	Yes	Not required
External Scientific Advisory Board	Yes	No
On-site/ reverse-site visits	Yes	As required
Pilot and feasibility project funding	Yes	No

NOTE:

- All applications to the Clinical Investigations Study Section, regardless of grant mechanism, must follow the Guidelines for Clinical Investigations Research and must include a Human Research Subject Plan. Clinical applications without such a plan will be administratively triaged.
- Applications proposing research with human subjects must be submitted to the Clinical Investigations Study Section, with the exception of studies using only human tissue (i.e. cell lines, blood, urine, etc.) without **ongoing** patient contact.
- All 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.

ELIGIBILITY:

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, 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. Applications may be submitted by domestic and foreign non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government. Ordinarily, for-profit organizations will not be considered, except under special circumstances (see the Industry Discovery & Development Partnerships section for description of special program for for-profit entities). There are no citizenship requirements and racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as principal investigators.

LETTER OF INTENT:

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

- Human Islet Transplantation
- Complications
- Autoimmunity and Prevention.

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

Grant Administrator, Juvenile Diabetes Research Foundation International
Attention: Letter of Intent
120 Wall Street, 19th Floor
New York, NY 10005-4001 USA

TERMS OF AWARD:

JDRF centers for Diabetes Research will be supported for a maximum of $2 million total costs per year for a period of up to 5 years. Indirect costs cannot exceed 10% of direct costs minus equipment costs and/or subcontract costs if indirect costs are included in the budget submitted by the subcontracting organization. Evidence of institutional commitment in the form of dollars or resources is also highly desirable. Support beyond 5 years will be determined based on a competitive review of the accomplishments and future plans of the center.

NOTE:

JDRF no longer accepts applications on the NIH PHS 398 application form or the JDRF Center and Program Project application form. You must apply via the proposalCENTRAL™ website (https://v2.ramscompany.com).

APPLICATION:

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

The Center proposal should contain the following: Administrative Information about the Center, a Table of Contents, Center overview and individual projects.

1. Administrative Information about the Center — Complete the following forms for the Center as a whole (applicants do not need to fill out the signature page as information is automatically transferred to this page):
    a. Title Page
    b. Applicant/Center Director
    c. Institution and Contacts
    d. Key Personnel
    e. Abstract
    g. Organization Assurances

2. Table of Contents — Prepare a detailed table of contents that will enable reviewers to find specific information readily. Use the table of contents template provided as part of the Center Overview. Organize the table of contents so that the Center Overview and each individual project and core are listed as headings in the table of contents.
   Identify each project by title, and assign each project a number and each core unit a capital letter, and provide the name of the investigator responsible for each component. Number the pages consecutively.

3. Center Overview — includes a description of the overall goals of the Center and each individual project, the relationship of the projects to each other and the Center and a composite budget for the entire Center. The Center Overview should not exceed 15 pages.

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

BUDGET:

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

Budgets should be quoted in United States dollars and provided for the entire project period. Up to a maximum of US $2 million per year total costs for up to five years may be requested.
Because clinical trials are a major activity of JDRF Centers, proper assurances on the safety of human subjects must be demonstrated. The applicant must provide a copy of the Institutional Review Board (IRB) approved consent form, or nearly finalized draft, with the application. Plans for the formation of a Data Safety Monitoring Board (DSMB) should also be presented. Finally, the dynamic and collaborative nature of a JDRF Center requires careful guidance and attention beyond the responsibilities of the Center Director or a single individual, and as such, an external scientific advisory board should be formed and plans for its function within the Center should be presented in the application.
If the application is approved for funding, no funds will be released until 1) IRB approval for the study is received AND 2) Final IRB-approved consent form is received.

REVIEW CONSIDERATIONS:

Applications will be grouped by topic and evaluated on a regular basis in accordance with the criteria described below. Evaluations will be competitive and performed by an appropriate peer and lay review group convened by the JDRF. Application deadlines and review dates will be communicated to the Center Director after review and approval of the LOI.

The JDRF Center review criteria will include:

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

SCIENTIFIC REVIEW:

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

LAY REVIEW:

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

JDRF BOARD REVIEW:

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

REVIEW CRITERIA OF INDIVIDUAL PROJECTS:

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

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

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

REVIEW OF CENTER PROJECT ASPECTS:

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

- Clarity of stated mission and goals and research plan
- Scientific, technical, or medical significance of the Center's projects
- Relevance — How relevant is the research proposed to the goals of the program, i.e. to target research at finding a cure for Type 1 diabetes and its complications that focuses on one of the areas described in the Request for Applications?
- Potential to develop and prove principle of new approaches to unsolved problems of Type 1 diabetes
- Scientific merit of the Center as a whole, as well as that of the individual research projects
- Appropriateness and adequacy of the experimental approach and methodology
- Investigators
    - Assessment of the leadership and scientific ability of the Director of the Center:
        - his or her ability to develop a program of integrated research projects with a well-defined central research focus;
        - and his/her commitment and ability to devote adequate time and effort to the program.
    - What is the role of each investigator as part of the Center: time commitment and who is going to do what? Will each investigator be able to devote adequate time and effort to the program?
- JDRF Centers are expected to have a clinical research component or show progress from basic research toward clinical application in years 1 through 5.
- For proposed clinical studies within the Center, review criteria will include soundness of the clinical study design, consideration of the potential benefits and risks to patients who will be involved in the research, plans to limit risks, and other ethical considerations.
- Innovation
- Synergy
    - Will there be a team of investigators with various types of expertise undertaking collaborative multidisciplinary research in the health sciences in various institutions?
    - Will there be research components, each scientifically meritorious, which together form an integrated research program able to address issues which could not readily be approached were the components to be funded separately?
    - Evaluation of the cohesiveness of the Center and the coordination and interrelationships of individual projects and core(s) to the common theme. What are the relative priorities of the various projects, is there a chronological relationship, and should they all be included in the Center?
- Appropriateness of the proposed budget and duration in relation to the proposed research.
- Availability of resources and facilities necessary to function as a Research Center
- Core facilities — Each core must provide essential facilities or services for two or more individual research projects. Review criteria for scientific cores consist of the following:
    - Justification and usefulness of the core facilities to the various research projects;
    - Relationship of each core to the central focus of the overall Center;
    - Quality of relevant facilities or services provided by the core (including procedures, techniques and quality control) and criteria for prioritization and usage;
    - Qualifications, competence and commitment of the Core leader and key personnel.
    - Demonstration of core resources that could expand to support non-JDRF funded projects and willingness to recruit third party funded researchers to participate in contributing to achieving the Center mission

- Quality of Informatics support, and clearly demonstrated opportunities for structured and unstructured information sharing
- Organization and Communication — Will the organizational aspects of the Center structure allow the proposed research to occur? Assessment of the plans for meetings, other interactions, and exchange of data, material and techniques. Comment on the geographical distribution of the Center members, keeping in mind that the inclusion of researchers from different centres was encouraged.
- Training — Will the research setting permit research training?
- Institutional and other sources of support — What is the institutional commitment to the Center and the impact of the Center on the institutions involved in terms of research priorities of the institution, financial support, time protection, and laboratory space and equipment? Are there any other sources of financial support for the request, which could include: cost-sharing arrangements with the sponsoring institution(s), industry (keeping in mind that university-industry collaborations were encouraged), or other agencies; estimates of institutional expenditures involved in upgrading or constructing laboratory facilities; estimates of indirect institutional support such as provision of services and computing resources; user fees.

EVALUATION:

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

8.0 JDRF Industry Discovery & Development Partnerships (IDDP)

NOTE:

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

☎ 212-479-7572

💻 pburn@jdrf.org

PURPOSE: NOTE: IF YOUR PROJECT INVOLVES CLINICAL STUDIES, CLICK HERE

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

Restore Beta Cell Function

-Regenerate the body's own beta cells

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

Restore Immunoregulation

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

Prevent, Postpone, Reverse Diabetic Complications

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

STRUCTURE:

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

APPLICATION:

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

☎ 212-479-7572

💻 pburn@jdrf.org

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

9.0 Scientific Guidelines

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.

9.1 Clinical Investigations Guidelines

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

C. CLINICAL STUDY DESIGN

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

1. Summary of proposed study objectives and design: Briefly state the goal of the study, describe the study design, and justify its use. If alternative study designs are possible (for example, randomized placebo control, cross-over, open label, etc.), discuss the reasons for choosing the proposed design. Identify the planned outcome measures and surrogate markers.

2. Subject recruitment and enrollment: Explicitly state inclusion and exclusion criteria for persons with Type 1 diabetes, at risk for Type 1 diabetes, family members, and healthy control subjects. Justify why these are chosen and discuss effect on potential recruitment where appropriate. Briefly describe plans for the type (health and disease status) and numbers of patients and controls to be enrolled, planned randomization procedures, and plans for how and over what duration study subjects will be recruited.

3. Study evaluation and statistical analysis: Include a brief non-technical description of how study results will be evaluated to support or provide evidence against the study hypothesis, including statistical methods to be employed. Include a rationale for proposed sample sizes. (This will generally rely on the typical distribution of the primary outcome measure in the target population and on anticipated effects in the study.) For clinical trials, include a power calculation. If applicable, provide alternative sample size and study design if a Bayesian analysis approach was adopted.

D. HUMAN RESEARCH SUBJECT PLAN

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

1. Criteria for subject inclusion/exclusion:
Describe the proposed involvement of human research subjects, including patients and healthy control subjects, stating their anticipated number, age range, sex, ethnic/racial background, and health status. Identify the criteria for inclusion or exclusion of any subpopulation, including children and adolescents. Include consideration of the privacy rights of both former and current patients. For example, address how previous guarantees of confidentiality in clinical or research settings will be honored in the way potential subjects are contacted.

2. Potential benefits and risks to subjects, plans to minimize risks and knowledge to be gained from the study:
In narrative format, for each proposed intervention and for each proposed subject group address the following factors1:

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

Note potential risks to pregnant women and fetuses.

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

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

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

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

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

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

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

6. Research subject informed consent:
Consent plans: Describe plans for the process for obtaining subject informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. Recognize that consent is an interactive process and that a signed form is merely evidence that the interaction took place.

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

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

Guidelines for the informed consent document are provided in Appendix C .
Submission of the finalized patient information and consent forms and written IRB approval will be required prior to initiation of funding.

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

8. Investigator education in the protection of human research subjects:
Describe, for all key personnel, education on the protection of human research subjects.

9. Projects involving drugs or devices
State whether the proposed clinical investigation involves the use of any drugs or devices and whether the drug or device is approved for the intended application. If not approved for the intended application, please indicate:
IND# or IDE#
Phase of the clinical study
Who holds the IND for this drug?
Submission of the FDA-IND letter, where applicable, will be required prior to initiation of funding.

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

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

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

APPENDIX B - U.S. Department of Health and Human Services Regulations Title 45 Part 46 Subpart D requirements for the participation of children in research
Subpart D of the human subjects regulations establishes requirements for research participation of children based on defined categories of potential risk and benefit of the research. The categories of research based on assessment on potential risks and benefits:
(1) No greater than minimal risk, where minimal risk means "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily

encountered in daily life or during the performance of routine physical or psychological examinations or tests"
(2) Greater than minimal risk and presenting the prospect of a direct benefit to the child, in which the anticipated benefit justifies the risk and is at least as favorable as that of alternative approaches
(3) A minor increase over minimal risk with no prospect of a direct benefit to the subject, but likely to yield generalizable knowledge about the child's disorder or condition that is of vital importance for the understanding or amelioration of the disorder or condition AND the intervention or procedure presents experiences to the child that are reasonably commensurate with those in the child's actual or expected medical, dental, psychological, social, or educational situations.
(4) Any other research, including research that poses more than a minor increase over minimal risk (for research in the United States and subject to the regulations, requiring the approval of the Secretary of Health and Human Services following consultation with a panel of experts and following publication and public comment).

APPENDIX C

INFORMATION TO BE INCLUDED IN THE CONSENT DOCUMENT

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

1. A statement that the study involves research; identification of the research sponsor(s), principal investigator(s), and institution(s) performing the research;
2. An explanation of the purpose of the research, an invitation to participate and explanation of why the subject was selected, and the expected duration of the subject's participation;
3. A description of procedures to be followed and identification of which procedures are investigational and which might be provided as standard care to the subject in another setting. Use of research methods such as randomization and placebo controls should be explained;
4. A description of any foreseeable risks or discomforts to the subject, an estimate of their probability and magnitude, and a description of what steps will be taken to minimize or prevent them; as well as acknowledgement of potentially foreseeable risks;
5. A description of any benefits to the subjects or to others that may reasonably be expected from the research, and an estimate of their likelihood;
6. A disclosure of any appropriate alternative procedures or courses of treatment that might be advantageous to the subject;
7. A statement, when applicable, that participation in the research may limit the subject's eligibility for participation in future research studies.
8. A statement describing to what extent records will be kept confidential, including examples of who may have access to research records such as hospital personnel, the FDA, the drug sponsors;
9. For research involving more than minimal risk, an explanation and description of any compensation and any medical treatments that are available if subjects are injured through participation; where further information can be obtained, and whom to contact in the event of a research-related injury;
10. An explanation of whom to contact for answers to questions about the research and the research subject's rights;
11. A statement disclosing the research sponsor(s).
12. A statement that research is voluntary and that refusal to participate or a decision to withdraw at any time will involve no penalty or loss of benefits to which the subject is otherwise entitled;

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

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.

9.2 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 JDF.

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 $1 M (USD) over three years must submit letters of intent to JDF. 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 to:

Juvenile Diabetes Research Foundation
Attention: Grant Administrator
120 Wall Street, 19th Floor
New York, NY 10005-4001 USA

An electronic copy of the letter should also be sent to:

Adrianne Wong, Ph.D.
awong@jdrf.org

Applicants will be notified within (6) weeks of receipt of letter 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:

Adrianne Wong, Ph.D.
212-479-7642
awong@jdrf.org

or

Robert Goldstein, M.D., Ph.D.
212-479-7523
rgoldstein@jdrf.org

9.3 Human Embryos in Stem Cell Research

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:

- The source of embryos
- The basic procedures of the protocol for the derivation of hES, including embryo screening protocols
- A plan for obtaining donor informed consent for the research use of embryos; submission of draft patient information and consent documents is required
- A statement as to why the use of human embryos is necessary to conduct the research

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:

- 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
- Documentation of required regulatory approvals (e.g., national and/or local licensing agencies)
- 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:

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 islet transplantation or letters of intent should be directed to:

Adrianne Wong, Ph.D.
☎ 212-479-7642
💻 awong@jdrf.org

9.4 Human Fetal Tissue in Research

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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