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## **Research on Biosamples from Type 1 Diabetes Clinical Trials, Genetics and Natural History Studies**

### ***Request for Applications***

**Release Date:** June 25, 2010

**Letter of Intent due Date:** September 1, 2010

**Application Receipt Date:** October 1, 2010

### **This RFA contains the following information:**

- Purpose of this RFA
- Background
- Research Objective and Scope
- Funds Available
- Eligibility
- Instructions to Submit An Application
- Review of Application
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### **Purpose of this RFA**

The goal of this RFA is to provide a funding mechanism to investigators for laboratory tests on non-renewable (non-DNA) samples generated by type 1 diabetes (T1D) clinical trials and studies. Applicants responding to this solicitation can choose to use samples from:

- Type 1 Diabetes TrialNet (<http://www.diabetestrialnet.org>) studies/trials including the Natural History Study, the Mycophenolate mofetil-Daclizumab (MMF/DZB) trial, and Rituximab (anti-CD20) trial
- The NIDDK Biosamples Repository (<https://www.niddkrepository.org/niddk/home.do>), which contains samples from the Type 1 Diabetes Prevention Trial-1 (DPT-1), and the Type 1 Diabetes Genetics Consortium (T1DGC)
- JDRF supported T1D trials
- non-JDRF supported T1D trials

Request for access to samples must be made directly with the relevant study groups, investigators, or companies in possession of samples prior to submission of an application. **Proof of access to samples is not required at the time of application submission, but will be required prior to award activation.** For each of the clinical studies, data sets are available and applicants are urged to obtain and review the data to assist in their preparation of the application. Information for obtaining data from the NIDDK studies is available on the NIDDK Repository website (<https://www.niddkrepository.org/niddk/home.do>). For non-NIDDK supported studies, requests for data sets must be made with the relevant study groups.

The principal investigator(s) and proposed research should bring to bear special expertise that will augment and enhance the knowledge gained from the original study, or address an independent and important question. The proposed research must be within the intent of the signed consent form for each study or trial; alternatively, the cost of reconsent must be strongly justified. Data generated shall be made available to other investigators through a data sharing network supported by JDRF. An appropriate data sharing plan conforming to JDRF's policy must be implemented.

### **Background**

NIH, JDRF and other non-profit or for-profit organizations have sponsored numerous immunotherapeutic clinical trials, genetics and natural history studies worldwide. Such trials/studies have generated valuable human biosample and data collections that provide a unique resource of high relevance to improving the current understanding of susceptibility and pathogenesis of Type 1 diabetes, as well as the mechanisms of therapeutic effect. Such knowledge can lead to improved treatments for T1D.

This initiative is intended to enable the application of new methods or the examination of hypotheses independent from or related to the questions addressed by the respective clinical trial/study, making use of material collected from one or more studies. This RFA is expected to promote scientific discoveries on disease mechanisms, disease pathogenic processes, and biomarkers of disease progression or clinical responses.

### **Research Objectives and Scope**

The goal of this RFA is the utilization of subject samples and/or data from clinical trials, genetics and natural history studies to study questions that are clinically relevant to Type 1 diabetes.

Examples of research topics may include, but are not limited to the following:

- Determination of the mechanisms of disease pathogenesis in T1D development
- Understanding of the mechanisms of action of T1D immunotherapies
- Identification of biomarkers of disease progression and/or therapeutic efficacy

This RFA will not support:

- Collection of new biological samples
- Any clinical intervention
- Studies using samples from transplantation or complications trials
- Exploratory research with animal models

Applicants are encouraged to contact JDRF program staff (see **Inquiries** section) to discuss whether the proposed research is within the scope of this RFA.

## **Funds Available**

JDRF intends to commit a maximum of US\$1,000,000 (including 10 percent indirect costs) through this mechanism, contingent upon the submission of a sufficient number of scientifically meritorious applications. The total project period for applications submitted in response to this RFA may not exceed two years. The Research Projects will be supported for up to \$165,000 per year (including 10 percent indirect costs).

## **Eligibility**

Applicants must hold an M.D., D.M.D., D.V.M., Ph.D., or equivalent academic degree and have a faculty position or equivalent at a college, university, medical school, or comparable institution. Applications may be submitted by foreign or domestic (United States) non-profit organizations, public or private, such as colleges, universities, hospitals, laboratories, units of state or local governments, eligible agencies of the federal government, or for-profit organizations. There are no citizenship requirements, and racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as principal investigators.

## **Instructions to Submit an Application**

### **LETTER OF INTENT**

Prospective applicants are requested to submit a letter of intent to apply to the RFA. This letter should include the name, telephone number, and mailing address of the Principal Investigator, the names of other key personnel, the name of the applicant institution, the title of this RFA, the title of the proposal and a list of the specific aims of the study. *Such a letter of intent is not binding and it will not enter into the review of any application subsequently submitted. Letters of intent are requested solely for planning purposes.* The JDRF staff will not provide responses to such letters. Letters of intent must be received no later than September 1, 2010 and should be submitted using JDRF's on-line application system, proposalCENTRAL (<http://proposalcentral.altum.com/default.asp?GMID=16>).

**Note:** When the LOI is administratively accepted, you will be able to access the full proposal template through proposalCENTRAL. Under the "Manage Proposals" tab you will find a list of applications "In Progress". When the LOI status changes to "LOI: Approved", you may click the [Edit](#) button to gain access to the full application.

### **APPLICATION PROCEDURES**

Applications in response to this RFA must be submitted using JDRF's on-line application system proposalCENTRAL (<http://proposalcentral.altum.com/default.asp?GMID=16>).

The research plan may not exceed seven pages, including figures and tables. Please note that the 7-page limit includes narrative items *a* through *d* as described below. Complete information should be included to permit review of each application without reference to previous applications. The research plan must address the requirements indicated above, and may be organized as follows: A) Specific Aims; B) Background and Significance of this work to JDRF and T1D; C) Preliminary Studies (if applicable); D) Research Design and Methods; E) Literature Cited (no page limit).

## **Review of Application**

### **Review Criteria**

Applications will be assessed as individual projects evaluating the investigators' potential to enhance the knowledge gained from the original trial/study, or to address scientific questions that are not

included among the original aims and that are not likely to attract funding by other mechanisms. The proposed projects will be evaluated for scientific merit by an external scientific review committee.

In considering the research plan, reviewers will be asked to assess whether extensive preliminary data has been provided and whether a staged approach to the use of samples has been applied to ensure the most effective use of the rare and valuable samples.

The scientific review group will address and consider each of the following criteria in assigning the application's overall score, weighting them as appropriate for each application.

- Evidence of access to samples/data
- Clinical relevance
- Approach
- Innovation
- Investigator/environment
- Data sharing plan

**ACCESS TO SAMPLES/DATA:** Documented proof of timely access to all material and information necessary for the project. Investigators should include (as an appendix to this application) details of the full sample access request application and all information provided by the study from which samples are requested. Proof of access to samples does not have to be demonstrated at the time of application submission, but will be required prior to award activation.

**CLINICAL RELEVANCE/SIGNIFICANCE:** Does this study address an important problem of clinical relevance? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced or improved? What will be the effect of these studies on the concepts or methods that drive this field?

Ideally, the related trial should be completed and unblinded. If the trial shows no or limited efficacy of therapy, a rationale for studying a subgroup of samples from this trial must be provided.

**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? Is the proposed research feasible within the term of the award?

**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:** Is the investigator appropriately trained and well-suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator 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?

**DATA SHARING PLAN:** Data generated shall be made available to other investigators through a data sharing network supported by JDRF. An appropriate data sharing plan conforming to JDRF's policy must be provided in the application.



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## **Lay Review**

Lay Review Committee (LRC) members will participate in the review. Each of the lay reviewers will be assigned applications in a manner similar 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. 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.

## **Board Review**

The recommendations of the review committee will be presented to the JDRF International Board for final approval before funds are awarded.

## **Terms of Award**

The Research Projects will be supported for up to \$165,000/year (including 10 percent indirect costs), for a period of 2 years. Although the size of award may vary with the scope of research proposed, applicants must stay within the budgetary guidelines noted above. Budgetary requests above this level must be strongly justified and require JDRF staff approval prior to application submission.

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.

NOTE: Proof of access to samples will be required prior to award activation.

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.

## **Application Receipt and Review Schedule**

Release Date: June 25, 2010

LOI Due Date: September 1, 2010

Application Receipt Date: October 1, 2010

Response to Applicants Date: December 15, 2010

Earliest Anticipated Start Date: February 1, 2011

## **Award Criteria**

Criteria that will be used to make award decisions include:

- Scientific merit and clinical relevance of the proposed project as determined by peer review
- Availability of funds
- Programmatic priorities

## **Inquiries**

For more information about this RFA, please contact:

### **Scientific Inquiries:**

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### **Administrative Inquiries:**

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### **PROPOSALCENTRAL**

<https://proposalcentral.altum.com/Login.asp>

(301) 916-4557 ext. 227, or toll free in the US, (800) 875-2562 ext. 227

[pcsupport@altum.com](mailto:pcsupport@altum.com)

Assistance can be obtained Monday through Friday between 8:30am and 5pm Eastern Time.