



















JDRF permits up to 20% of funds to be reallocated per budget line-item categories without prior JDRF approval. Any reallocation of funds exceeding 20% of budget line-item categories must have **prior approval** from JDRF.

#### **4.5.2 For Grants greater than \$500,000 (USD) per year**

JDRF permits up to 10% of funds to be reallocated per budget line-item categories without prior JDRF approval. For multi-project grants, the threshold applies to the total grant amount across all sub-projects. Any reallocation of funds exceeding 10% of budget line-item categories must have **prior approval** from JDRF.

#### **4.6 Changes in Percent Effort for Key Personnel**

The Grantee Institution must submit a written request to JDRF if the PI or key personnel will change the time devoted to the project by 10 percent or more from the level that was approved at the time of award (for example, a proposed change from 30 percent effort to 27 percent). This requirement is irrespective of the budget implications specified in section 4.5. Reallocation of percent effort on a project after the end date of an award is not permitted on JDRF awards.

JDRF must approve any alternate arrangement proposed by the Grantee Institution, including any replacement of the PI or key personnel named in the budget. JDRF reserves the right to modify the terms of the award, suspend payment, or terminate the award if the change in key personnel is deemed unacceptable.

Please see [JDRF Administrative Resources](#) for further requirements on changes that may impact the approved budget.

#### **4.7 Leave of Absence**

A Principal Investigator's leave of absence (LOA), including maternity and paternity leave, must be submitted in writing to JDRF within 30 days of the start date of the LOA. The LOA must include an appropriate justification for the leave of absence, the start and end dates of the LOA, the signature of the PI, and signature of the Grantee Institution's authorized signing official.

#### **4.8 Transfers**

In the event that the PI transfers to a new institution, a request to change the grantee institution must be submitted in writing to JDRF. JDRF will consider such a request provided that the original Grantee Institution will relinquish the grant and that the new grantee institution will accept the grant and JDRF's Terms and Conditions. The original grant period and total commitment remain the same. Administrative delays on the part of either the former or new grantee institution may negatively impact JDRF's decision to approve the transfer request.

The request to transfer grantee institutions must be made in advance of the anticipated start date at the new institution. See [JDRF Administrative Resources](#) for specific procedures.

Except as provided in this Section 4.8, the Grantee Institution may not assign its rights or responsibilities under the grant award, in whole or in part, without the prior written consent of JDRF.

JDRF Postdoctoral Fellowship and Advanced Postdoctoral Fellowship recipients must retain the same Mentor for the duration of their JDRF award. Training grant recipients may only transfer institutions if their Mentor is also transferring to the same institution.

### **5. Monitoring & Reporting**

#### **5.1 Activation**

Following receipt of the funding letter, the Grantee Institution is required to complete and submit activation materials. Materials are customarily due 1 – 2 months prior to the anticipated grant start date.

## **5.2 Yearly Progress Reporting**

For multi-year grants, a yearly progress report (renewal) must be filed by the Grantee Institution no later than 60 days prior to the start of each new funding period. See 7.1 for noncompliance to this requirement.

## **5.3 Final Progress Reporting**

For all grants, a final scientific progress report is required within 75 days of the end of the grant period. Final progress reports are also required for all grants that have been terminated (initiated either by JDRF or by the Grantee Institution). Failure of the Grantee Institution to submit a required final progress report may result in payment delays or suspensions. See 7.1 for noncompliance to this requirement.

## **5.4 Additional Progress Reporting**

In addition to the annual and final progress reports, some JDRF awards may require the Grantee Institution to file progress reports more frequently. Reporting above and beyond the annual and final progress reports will be clearly defined in the funding letter for the individual grant and/or via official correspondence regarding changes to the terms during the life of the grant. See 7.1 for noncompliance to this requirement.

## **5.5 Expenditure Reporting**

An expenditure report is due within 75 days after the end of each funding period.

## **5.6 Intellectual Property, Invention Reporting, & Royalties**

The mission of JDRF is to find a cure for Type 1 diabetes and its complications through the support of research. In furtherance of this mission, JDRF provides funding to various research institutions (each a “Research Institution”) to conduct research in connection with the cure, treatment and prevention of Type 1 diabetes and its complications. This policy on intellectual property, commercialization and royalties (the “Policy”) applies to all Research Institutions that receive funding from JDRF, including the Grantee Institution. By accepting funding from JDRF, the Grantee Institution agrees that it is bound by all terms and conditions specified in this Policy.

### **5.6.1 Intellectual Property Rights in the Research Results**

As between JDRF and the Grantee Institution, the Grantee Institution will own all right, title and interest, including to the extent applicable, all patent, copyright, trademark, and other legal rights, in and to all Inventions (whether or not patentable), products of the mind, tools, scientific discoveries, technological advances, compilations, computer software, printed materials and other works of authorship created, made, conceived or reduced to practice by the Grantee Institution or any of its employees, investigators, students, staff or collaborators at other institutions (collectively, “Investigators”) in the course of conducting research using funding provided by JDRF (collectively, the “Research Results”). To the extent that the Grantee Institution’s own policies permit individual Investigators to own any right, title or interest in any Research Results, the Grantee Institution shall ensure that each Investigator complies with the provisions of this Policy with respect to such Research Results.

To the extent not restricted by Federal or State laws or regulations governing the Grantee Institution, the Grantee Institution shall require any subcontractor that it engages to conduct research using funding provided by JDRF to agree to be bound by this Policy to the same extent as the Grantee Institution is bound. The Grantee Institution shall provide a copy of this Policy to all such subcontractors.

[pull from RMS360 award number; PI last name]

The Grantee Institution hereby grants to JDRF an irrevocable, non-exclusive, worldwide, fully paid-up, royalty-free, perpetual license, with the right to grant sublicenses to others, to use and to practice all Research Results for non-commercial research purposes related to the diagnosis, cure, treatment and/or prevention of Type 1 diabetes and its complications. JDRF will notify the Grantee Institution when it intends to grant a sublicense pursuant to the terms herein, and will identify the intended sublicensee to the Grantee Institution. JDRF will consider in good faith any reasonable concern or objection raised by the Grantee Institution with respect to an intended sublicense.

### **5.6.2 Other Intellectual Property of the Grantee Institution or Third Parties**

This Policy does not apply to any patents, copyrights, trademarks or other intellectual property of the Grantee Institution that was not developed under JDRF funding. Unless agreed to otherwise in writing, this Policy does not apply to any patents, copyrights, trademarks or other intellectual property owned by third parties and not developed under JDRF funding.

### **5.6.3 Invention Disclosures**

The Grantee Institution shall disclose to JDRF within 60 days all inventions (including without limitation any device, process, method, composition or system) that are conceived or first actually reduced to practice by the Grantee Institution or any of its Investigators during the course of carrying out any research using funding provided by JDRF (each an "Invention") that are potentially patentable. The Grantee Institution shall make such disclosure via JDRF's RMS360. The report shall include a brief description of the Invention, its potential commercial use, a list of all inventors, and the Grantee Institution's plan for protecting the invention (i.e., filing of a patent application, trademark or copyright application) and any plans for commercializing the Invention, including a list of any potential licensees.

### **5.6.4 Patents**

As between JDRF and the Grantee Institution, the Grantee Institution will have the first right to pursue patent protection for Inventions. In the event that the Grantee Institution chooses not to pursue patent protection for any Invention in any jurisdiction or country, or abandons or intends to abandon a patent application or an issued patent claiming any Invention in any jurisdiction or country, the Grantee Institution shall promptly inform JDRF of such decision, and at JDRF's request, the Grantee Institution shall assign, license or otherwise transfer any or all rights in or control of such Invention in such jurisdiction to JDRF.

The Grantee Institution shall notify JDRF of its intention to abandon in any jurisdiction or country any patent application claiming an Invention or any issued patent claiming an Invention at least ninety (90) days in advance of any deadline that would cause such application or patent to be abandoned or otherwise lapse in such jurisdiction or country, and of its intention not to pursue patent protection for any Invention in any jurisdiction or country at least ninety (90) days in advance of any statutory bar that would prevent JDRF from obtaining patent protection for such Invention in such jurisdiction.

### **5.6.5 Commercialization**

#### **5.6.5(a) Commercialization Efforts**

Upon the disclosure of a new Invention or generation of any other Research Results, the Grantee Institution shall take appropriate steps to commercialize such Research Results in a timely fashion, either itself or through one or more licensees, in the field of diagnosing, curing, treating, and/or preventing Type 1 diabetes and its complications. If JDRF determines in good faith, after consulting with the Grantee Institution, that the Grantee Institution has not itself or through one or more licensees diligently pursued commercialization of any Research Results in the field of diagnosing, curing, treating, and/or preventing Type 1 diabetes and its complications within a commercially reasonable period of time, then at JDRF's request the Grantee Institution shall meet with JDRF to discuss a commercialization plan for the Research Results that is reasonably satisfactory to JDRF. If the Grantee Institution is unable to commercialize the Research Results within the timeframe specified in the

commercialization plan, then at JDRF's request the Grantee Institution shall assign, license or otherwise transfer any or all rights in or control of such Research Results to JDRF, unless the Grantee Institution can show reasonable cause as to why it should retain title to or control of such Research Results.

### **5.6.5(b) Commercial Licenses**

(1). Notice of Intention to Grant Licenses or other Transfers. The Grantee Institution shall provide JDRF with written notice of its intention to transfer, sell, license, assign, or otherwise grant any party the exclusive or non-exclusive right to use or practice any Research Results (hereinafter collectively a "License") at least 60 days prior to granting such License. Such notice shall describe in reasonable detail the proposed License to be granted, including without limitation: (a) a detailed description of the Research Results to be transferred; (b) the facts and circumstances pertinent to the Grantee Institution's decision to grant the License; (c) the nature, terms and conditions of the License; and (d) the identity of the prospective licensee.

(2). Non-Exclusive Licenses. The Grantee Institution shall have the right to grant a non-exclusive License of any Research Results, provided that the Grantee Institution reasonably believes that granting of such non-exclusive License would not have a material adverse effect on the value (commercial or otherwise) of such Research Results.

(3). Exclusive Licenses. Concurrently with providing JDRF with written notification pursuant to Section 5.6.5(b)(1) of this Policy, the Grantee Institution shall initiate consultation with JDRF concerning any proposal by the Grantee Institution to grant an exclusive License of any Research Results. To facilitate consultation, the Grantee Institution shall supply JDRF with a draft of the proposed exclusive License. At its discretion, JDRF may comment either verbally or in writing on a proposal by the Grantee Institution to grant an exclusive License and/or on the provisions of the draft exclusive License. If JDRF comments in writing, then the Grantee Institution shall respond to JDRF's comments in writing. With respect to any decision regarding whether to grant an exclusive License, the Grantee Institution and JDRF further agree to (a) act responsively, cooperatively and in good faith, and (b) make such decisions on a reasonable basis using the principles and guidelines set forth in Section 5.6.5(b)(4) of this Policy.

(4). Principles and Guidelines for Granting Exclusive Licenses.

(a) Basic Principles and Guidelines. The Grantee Institution and JDRF agree that an exclusive License should be granted if and only if the granting of such exclusive License is reasonably likely to: (i) maximize the positive impact of the subject matter of the License on the health and well-being of Type 1 diabetes patients; (ii) maximize the availability of diagnostic or therapeutic products to Type 1 diabetes patients; and (iii) maximize the speed at which diagnostic or therapeutic products are available to Type 1 diabetes patients.

(b) Exclusive License Agreement Principles and Guidelines. In addition to the basic principles and guidelines set forth in Section 5.6.5(b)(4)(a) of this Policy, the Grantee Institution and JDRF further agree that an exclusive License should be granted if and only if the terms and conditions of the exclusive License incorporate the following elements: (i) reasonable performance milestones and a demonstrated capacity of the licensee to be able to meet those milestones; (ii) termination or conversion to nonexclusivity provisions in the event the licensee does not meet specified milestones; and (iii) reasonable business terms and conditions that are in keeping with the then existing market standards for such type and nature with respect to similar technology and in similar disease indications.

### **5.6.6 Transfer of Research Results to JDRF; Commercialization by JDRF**

In the event of an assignment or other transfer to JDRF of any rights in or control of any Research Results as provided in this Policy, the Grantee Institution shall cooperate with JDRF (at JDRF's expense) and shall execute or cause to be executed such documents and take or cause to be taken such other actions as

reasonably may be requested by JDRF in order to effectuate such transfer. After the effective date of any such transfer, as between the Grantee Institution and JDRF, JDRF shall be solely responsible for all costs associated with the Research Results, including but not limited to filing, prosecuting and maintaining patent applications and patents.

In the event that JDRF commercializes a product the making, use, sale or import of which incorporates the transferred Research Results, or would infringe any intellectual property rights associated with the transferred Research Results absent the transfer to JDRF, JDRF shall negotiate in good faith with the Grantee Institution a reasonable royalty rate that will be payable to the Grantee Institution based on sales of such product, taking into consideration the financial contribution of both JDRF and the Grantee Institution. In addition, in the event that JDRF's making, use, sale or import of any product would infringe an intellectual property right associated with Research Results owned by the Grantee Institution and not transferred to JDRF, then the Grantee Institution shall grant to JDRF an irrevocable, non-exclusive, worldwide, fully paid-up, royalty-free, perpetual license, with the right to grant sublicenses to others, to use and to practice those Research Results to the extent reasonably necessary to commercialize such product, and to the extent that the Grantee Institution has the authority to grant such rights. In the event that JDRF's making, use, sale or import of any product would infringe an intellectual property right associated with inventions or other research results owned by the Grantee Institution and not funded by JDRF, then the Grantee Institution shall reasonably negotiate with JDRF with respect to any such intellectual property rights that JDRF would require in order to commercialize such product, to the extent that the Grantee Institution has the authority to grant such rights.

#### **5.6.7 Royalties/Reimbursement of Patent Costs**

In acknowledgement of JDRF's provision of funding, the Grantee Institution shall pay to JDRF a royalty in the amount of ten percent (10%) of Net Income, up to an aggregate amount equal to five (5) times the total funding provided by JDRF to the Grantee Institution in connection with the grant under which the applicable Research Results were developed. For these purposes, "Net Income" shall mean all revenues and other consideration (including equity) received by the Grantee Institution from the licensing, sale, transfer or other commercial utilization of any Research Results, less payments that the Grantee Institution makes to any applicable inventors in accordance with the Grantee Institution's policies and less direct, unreimbursed out-of-pocket expenses paid by the Grantee Institution to third parties for patenting or licensing any Research Results. If the Grantee Institution receives an equity interest, including without limitation options, warrants, convertible securities or other similar rights, agreements, arrangements or commitments, or any other right to invest or receive an economic interest in a company (including, but not only, companies founded through the Grantee Institution) in connection with the licensing or other commercial exploitation of the Research Results, in lieu of or in addition to revenue, JDRF shall receive 10% of such consideration by a direct grant to JDRF.

The Grantee Institution shall make all such payments to JDRF at least annually, within ninety (90) days after the end of each calendar year in which such Net Income was received by the Grantee Institution, or within such other period to which the parties mutually agree. The Grantee Institution shall provide to JDRF, upon request, financial information adequate to establish and document the amount of Net Income. JDRF also shall have the right to audit the Grantee Institution's books and records annually in order to verify the Net Income. The Grantee Institution's obligation to pay royalties to JDRF shall survive indefinitely after the expiration and/or termination of the JDRF award.

In the event that JDRF has funded the patent costs of any Invention or intellectual property costs of any other Research Results that are not assigned or transferred to JDRF and that are later licensed, sold, or otherwise transferred by the Grantee Institution to a third party for commercialization, the Grantee Institution shall require such third party, as a condition of such license, sale or other transfer, to reimburse JDRF for all prior funding of such costs, which shall be in addition to any other amounts required to be paid to JDRF hereunder.

JDRF reserves the right, at the option of the Grantee Institution, to participate in future equity/financing opportunities, in which the Grantee Institution has reserved a similar right, with companies founded involving IP or technology developed as a result of JDRF funding and/or licensed or transferred to another entity. This includes companies formed by or incubated at the Grantee Institution or independent of the Grantee Institution, whose work stems from or builds on research funded by JDRF. Grantee Institution and/or Company will notify JDRF at least 60 days in advance if they plan to enter into an equity or financing arrangement related to the Research Results of JDRF funding.

### **5.6.8 Reporting**

The Grantee Institution shall report to JDRF within sixty (60) days of the receipt of any invention disclosure, the filing of any patent application claiming any Invention, the issuance of any patent claiming any Invention, the filing of any application to register a copyright or trademark in any Research Results, and the execution of any agreement granting any third party the right to use or practice any Inventions or other Research Results (whether for research, development, commercial or other purposes). In addition, the Grantee Institution shall promptly report to JDRF any decision to abandon or not pursue patent protection on any Invention. With each such report, the Grantee Institution shall provide JDRF with copies of such patent applications or issued patents, copies of such copyright or trademark applications, and copies of any such agreements with a third party. JDRF shall maintain these documents in confidence as provided in this Policy.

In addition, the Grantee Institution shall submit annual reports to JDRF describing the status of JDRF-funded research, the Research Results (including a description of any intellectual property rights other than Inventions that have been developed), the Grantee Institution's efforts to seek patent protection for, develop and commercialize Inventions and other Research Results, and, if applicable, setting forth the Net Income for such year. Such reports shall include the status of such development, the names of current or potential licensees, the relevant terms of any licenses that are in negotiation or have been executed granting any third party the right to use or practice any Inventions or other Research Results, and the receipt of any royalties and other consideration under such licenses. This requirement does not supersede notification requirements outlined in 5.6.5(b) and 5.6.7.

The Grantee Institution is required to report invention disclosures, patent applications, patent allowances and/or the execution of IP Transfer Agreements (as stated above) related to JDRF supported inventions to JDRF for a period of three (3) years after the expiration and/or termination of the JDRF award. The Grantee Institution agrees to keep JDRF informed of the status of any Invention disclosure or patent application filed related to a JDRF supported invention. At JDRF's request, the Grantee Institution will provide JDRF with copies of invention disclosures, patent applications, patent allowances and any IP Transfer Agreements. Such information will be for JDRF-internal purposes only and will be considered confidential. All reports shall be submitted via JDRF's RMS360. The Grantee Institution's obligation to report to JDRF shall survive after funding has terminated.

### **5.6.9 Cooperation**

As reasonably requested by JDRF, the Grantee Institution shall from time to time consult with JDRF with respect to matters relating to JDRF-funded research, including matters relating to the patenting, development and commercialization of Inventions and other Research Results. For example, if so requested by JDRF, the Grantee Institution shall discuss with JDRF the ongoing progress of JDRF-funded research, critically assess the results of such research, identify and address any weaknesses or delays in research or commercialization, and determine when and whether particular research or commercialization targets are achieved.

In making decisions whether to continue ongoing grants or whether to award additional grants to a researcher or his/her institution, JDRF will consider whether the Grantee Institution has honored the above Policy.

### **5.7 Publication Requirements**

The Grantee Institution is expected to publish in relevant scientific journals and to provide information to the public on objectives, methodology, and findings resulting from their JDRF-supported research activities. The Grantee Institution must notify JDRF Grant Personnel of any publication relating to JDRF-supported research. Copies of abstracts and journal articles (preprints and reprints) should be included as a component of the Grantee Institution's yearly grant renewal, or may be submitted anytime during the grant year through RMS360.

The Grantee Institution is required to submit all full-length peer-reviewed publications resulting from JDRF funding to JDRF prior to the publication date. JDRF will honor all embargos.

## 5.8 Public Access Policy

To ensure the scientific knowledge generated by JDRF funding can be accessed, read, applied and built upon in fulfillment of our organizational goals, JDRF expects its researchers to publish their findings in peer-reviewed journals. It is a condition of JDRF funding that all peer-reviewed articles supported in whole or in part by its grants be made available in the PubMed Central online archive in accordance with the following conditions:

- Authors are to deposit an electronic copy of their final peer-reviewed manuscripts in PubMed Central immediately upon acceptance for journal publication.
- The manuscript is to be made publicly available in PubMed Central no later than 12 months after the official date of journal publication.
- An author must acknowledge JDRF support in every article arising from such funding. The acknowledgement statement must include the applicable JDRF grant number. This will enable JDRF to link the published outputs of research to the support it has provided.

PubMed Central is a database of full-text biomedical journal articles available online without a fee. It is hosted by the National Library of Medicine in the National Institutes of Health. Once posted in PubMed Central, results of research become more accessible, prominent, and integrated within the context of other research findings, making it easier for scientists worldwide to pursue T1D research. Equally important, families, clinicians, patients, educators, funders, and students reap the benefits of information arising from funding by accessing publications on PubMed Central at no charge. An author must acknowledge JDRF support in every article arising from such funding. The acknowledgement statement must include the applicable JDRF award number. This will enable JDRF to link the published outputs of research to the support it has provided.

Resources regarding JDRF's public access policy can be found within [JDRF Administrative Resources](#).

## 5.9 Public Announcements

Any public announcement (i.e. press release, website posting, public email announcement) must be coordinated with JDRF. Please contact the Public Relations and Communications team regarding such announcements (e-mail: [media@jdrf.org](mailto:media@jdrf.org)).

## 5.10 Record Retention

As per JDRF policy and Generally Accepted Accounting Principles (GAAP), the Grantee Institution is expected to retain both financial and programmatic records (either electronic or paper) relating to any JDRF grant for a period of at least 7 years.

## 5.11 Auditing

JDRF reserves the right to audit all expenses related to JDRF awards at any time. As a condition of accepting this award, the Grantee Institution agrees to maintain books and records documenting the expenditure of JDRF's grant funds in accordance with customary accounting procedures. The Grantee Institution further agrees to make these books and records available to JDRF for review (at JDRF's expense) upon request.

JDRF may audit grant expenses in order to receive assurance of the following:

1. The Grantee Institution is complying with JDRF grant terms and conditions, as well as applicable laws and/or regulations
2. Desired grant/scientific outcomes, results, and objectives are being achieved
3. Resources are being managed properly
4. Financial operations are conducted appropriately
5. Financial reports are accurate and on time

If the Grantee Institution's submitted information demonstrates financial and/or grant management deficiencies as they relate to any JDRF-funded project (either based on audit summaries or via JDRF review of general ledger), JDRF may require a formal plan of action from the Grantee Institution in the form of a letter or memorandum from the Grantee Institution's administrative or financial officer, stating the corrective actions to be taken and the timeline for action.

### **5.11.1 Independent Audit Reports**

U.S. and Canadian organizations/institutions that expend more than \$750,000 per year in U.S. Federal award funds must conduct an independent yearly audit. As a component of JDRF's auditing and monitoring practices, JDRF reserves the right to review the Grantee Institution's audit report upon request. For international Grantee Institutions, or for U.S./Canadian Grantee Institutions that expend less than \$750,000 per year in U.S. Federal award funds, equivalent yearly audit reports would suffice. For a Grantee Institution that does not conduct an independent external audit, an official letter signed by a Grantee Institution official may be submitted instead of the audit report. The letter must state that the Grantee Institution has financial and operational internal controls in place to successfully manage the JDRF grant.

### **5.11.2 Site Visits & Evaluations**

Site visits and evaluations may occur annually for any JDRF grant. The Grantee Institution will be notified in advance of an upcoming on-site evaluation and will work with their JDRF scientific program manager and/or grant administrator to determine the evaluation structure. Most JDRF awards greater than \$500,000 U.S. per year may be subjected to a more formal evaluation. In these cases, the JDRF research program personnel will work with the Grantee Institution to identify members of an Evaluation Committee as a method in which to receive third party, expert feedback on the progress of the project. At the end of an evaluation, JDRF program personnel will provide the PI with an evaluation summary statement, to which the PI may be required to respond. Payments for subsequent funding periods may be tied to evaluation results and/or the PI's response to the evaluation summary statement.

## **6 Clinical Trials**

### **6.1 Clinicaltrials.gov**

Grantee Institution is required to register all non-exempt human subject studies in the [Clinicaltrials.gov](https://clinicaltrials.gov) database (including [applicable clinical trials](#)) to ensure information is freely available on JDRF funded trials within the T1D community. The registration should be no later than 21 days after the first subject is enrolled,



and kept up to date and updated no less than every six months while recruitment is active. The applicable NCT# must be added to the grant record in RMS360.

## 6.2 Antidote Bridge

Grantee Institution is also encouraged to register all non-exempt human subject studies in the [Antidote Bridge platform](#).

## 6.3 Clinically Meaningful Outcomes

The Steering Committee of the T1D Outcomes Program has [defined](#) the following outcomes: hypoglycemia, hyperglycemia, time-in-range, and diabetic ketoacidosis (DKA). JDRF requires that all newly funded clinical studies incorporate the appropriate outcomes. Further, outcomes incorporated into a study should be consistent with the definitions from the publication, and we recommend their usage as endpoints in all T1D studies. Protocols that include measurement of these outcomes that are not defined per the publication must provide justification prior to grant approval. Please contact Clinical Trial Manager Shachi Vyas ([svyas@jdrf.org](mailto:svyas@jdrf.org)) with any questions.

## 6.4 Communication to Clinical Trial Participants

Clinical trial participants should be provided with a lay summary of results from the clinical trial at the time of data presentation and/or publication to the scientific community and/or the public. JDRF funded investigators, their staff or IRB members shall not promote or advertise in any context (informed consent form, protocol, study report, etc.) that an investigational new drug, biologic or device is safe or effective in any context for the purpose it is being investigated. This prohibition is to avoid any promotional or commercialization claims prior to regulatory approval. However, dissemination of the clinical trial's scientific findings/study results to the scientific and T1D community is permissible. Grantees must comply with country-specific regulations in sharing study results with trial participants (e.g. 21 CFR 312.7, 812.7)

## 7. Termination and Enforcement Actions

### 7.1 Suspension & Administrative Probation

JDRF reserves the right to withhold grant payments on an award at any time, in cases where the Grantee Institution is non-compliant. Such cases include, but are not limited to, failure to submit proper documentation by its respective due date (e.g., expenditure reports, IRB/IAUCC approvals, etc.) and unsatisfactory scientific progress. In addition, JDRF may place the PI and/or his/her Grantee Institution on administrative probation if outstanding documentation or other administrative issues exceed a 90-day period or if the Grantee Institution is non-compliant as outlined in this document. JDRF administrative probation may include, but is not limited to, the following actions:

1. Withholding of all payments for the grant/project in question
2. Changing to a payment reimbursement schedule
3. Withholding of all JDRF payments for the PI, for any JDRF grant
4. Withholding of all JDRF payments for the Grantee Institution, for any JDRF grant
5. Any combination of the above

A PI under administrative probation will have the opportunity to respond to the probation by sending a rebuttal letter to JDRF within 15 days of the probation's notification, at which time JDRF will make a final decision on the suitable course of action (see Grant Appeals Procedures, below). Payments will be reinstated when all outstanding documentation has been processed and approved by JDRF and/or all required corrective

measures have been taken and documented. (It is strongly suggested that the Grantee Institution contact JDRF in advance should they anticipate any delays in submitting required documentation.)

If, after the probation period, any Grantee Institution fails to comply, further action may be taken, including but not limited to, the termination of award (see below).

## **7.2 Termination**

### **7.2.1 JDRF Termination for Convenience**

JDRF reserves the right to terminate an award at any time, in whole or in part, with or without cause.

### **7.2.2 JDRF Termination For Cause**

JDRF may terminate an award at any time for cause, including financial, ethical, administrative or programmatic insufficiencies or the failure of the Grantee Institution to comply with these Terms and Conditions. Generally, JDRF will allow the Grantee Institution to take corrective measures should the possibility of termination arise from financial, ethical, administrative, or programmatic insufficiencies. In such cases, the award will be suspended until corrective actions are taken as outlined by JDRF. Notwithstanding that JDRF may permit the Grantee Institution to take corrective actions or offer probation, JDRF is not required to do so before terminating an award. A termination of the award for cause will not relieve the Grantee Institution of any breach of these Terms and Conditions or any other requirements of the award.

### **7.2.3 Grantee Termination**

Awards may also be terminated at any time by the Grantee Institution, in whole or in part, with or without cause. In such cases, the Grantee Institution must provide JDRF with written documentation of the reasons for termination. If a Grantee Institution elects to terminate a portion of their award, JDRF may determine that the remainder of the grant no longer meets JDRF research mandates and may elect to terminate the remainder of the entire award.

## **7.3 Modification of the Terms of the Award**

During the grant period, should JDRF science or grant personnel identify financial, administrative, or programmatic insufficiencies, JDRF may place special conditions on the award (some of which are outlined in sections 7.1 and 7.2, above) if corrective actions are required. If special award conditions must be imposed, JDRF will notify the Grantee Institution, in writing, of the nature of the special conditions, why they are being imposed, what corrective action the Grantee Institution can take to correct the problem(s), and the timeline for complying. JDRF may also require the withdrawal of PI or other key personnel should JDRF conclude that the PI and/or other key personnel are no longer competent to perform. Should this be the case, JDRF may require that the Grantee Institution select a new PI and/or key personnel. All decisions to modify the terms of an award (including withdrawal of PI or other personnel, or other special circumstances or conditions) will be exercised at JDRF's discretion.

## **7.4 Recovery of Funds**

Should the Grantee Institution be paid in excess of the amount for which it is eventually determined to be eligible under the terms of the grant (i.e., due to error, misspent funds or unallowable costs), JDRF may administratively recover those funds. JDRF may require the Grantee Institution to pay back funds, and will specify the terms and timeline for repayment. Additionally, JDRF has the right to set off such amounts against any payment obligations of JDRF to the Grantee Institution, including payments due from JDRF under other grant awards. JDRF may take any other actions permitted by law to recover such funds.

## 8. Grant Appeals Procedures / Rebuttal

A PI under Administrative Probation or who has been given notice of other JDRF corrective action (based on ethical or financial misconduct, negative audit findings, or other actions as outlined in this document) will have the opportunity to respond to the probation or corrective action required by JDRF. The Grantee Institution must send a rebuttal letter to JDRF within 15 days of the probation/corrective action notification, at which time JDRF will make a final decision on the suitable course of action and will notify the Grantee Institution as such.

The authorized person identified below, by his or her electronic signature in RMS360 on the date below, acknowledged that he or she read and agreed to these Terms and Conditions.

Authorized signing official full name: [typed in upon accepting T&Cs in RMS]

Institutional Email Address: [automatically from RMS]

Execution date and time: [automatically from RMS]

SAMPLE