



TYPE 1  
DIABETES  
**GRAND  
CHALLENGE**

## **Terms and Conditions**

### **under which a Type 1 Diabetes Grand Challenge Grant is Awarded**

The JDRF UK Terms and Conditions apply to all UK and international grantees. JDRF UK is committed to ensuring that all grant management and oversight requirements are met. To accomplish this goal, JDRF UK's funded organisations/institutions must comply with the grant terms and conditions outlined here.

By accepting the grant, the Award Holder (AH) and the Grantee Institution agree with JDRF and the Funder to be legally bound to these Terms and Conditions. It is the responsibility of the Grantee Institution's Financial Officials and Research Officers to ensure that all documentation submitted to JDRF UK conforms to the Terms and Conditions. JDRF UK allows the Grantee Institution and AH to manage their grant's day-to-day activities following the Grantee Institution's established policies, procedures, and practices so long as they are equivalent to (or more rigorous than) JDRF UK's policy and requirements required under these Terms and Conditions.

### **Background**

This agreement sets out the Terms and Conditions by which JDRF UK and the Funder have agreed to award the whole or part of the grant to the institution, as funded by SMF.

The obligations of the AH and Grantee Institution in these terms and conditions are owed to each of JDRF UK and the Funder separately (including those expressed to be owed only to JDRF UK) and the rights of JDRF UK and the Funder under these Terms and Conditions may be enforced by each of JDRF UK and the Funder separately.

### **Definitions**

The following terms shall have the following meanings:

|                               |   |
|-------------------------------|---|
| Application                   | The application for funding submitted to JDRF UK by the Award Holder in order to carry out the Research.  |
| Arising Intellectual Property | Includes all inventions, discoveries, materials, technologies, products, data, algorithms, software, patents, databases, copyright, trademarks, know-how and all other intellectual property rights and similar or equivalent rights anywhere in the world which currently exist or are recognised in the future and including applications, extensions and renewals in relation to any such rights, generated or validated under the Research. |
| Award                         | The grant to be provided by JDRF UK (funded by SMF) for the performance of the Research as identified in the Award Letter.  |
| Activation Materials          | The materials sent to the Award Holder after JDRF UK's acceptance of the Application Form for funding and which must be submitted to JDRF UK by the Award Holder and Grantee Institution  |

|                        |   |
|------------------------|---|
|                        | confirming the date upon which the project activities will commence and the first instalment of the Award should be paid.   |
| Award Holder           | The principal investigator on the Application and the person who has responsibility for the leadership of the Research.   |
| Award Letter           | The letter from JDRF UK and the Funder to the Grantee Institution, signed by an authorised representative of JDRF UK and the Funder, specifying the Award title, amount awarded, the duration of the Award and any additional terms and conditions.   |
| Co-applicant           | A person who assists the Award Holder in the management and leadership of the Research.   |
| Collaborator           | A person who makes a significant material or intellectual contribution to the Research.   |
| Conflicting Activities | Has the meaning given in Section 1.3.   |
| Contract               | The agreement between the Award Holder, the Grantee Institution, JDRF UK and the Funder which is made up of the Application, these Terms and the Award Letter counter-signed by the Grantee Institution.  |
| Follow Up Report       | The report provided 18 months after the end of the Award, including final results, data, publication(s) resulting from the Research and outcomes of applications for future funding or future development.  |
| Funder                 | The Steve Morgan Foundation (see below at SMF).   |
| Grantee Institution    | The University, NHS Trust or other legal entity to which the Award is granted and which is the Award Holder's employer.   |
| JDRF UK                | The charity operating under the name of JDRF. JDRF is a registered charity in England and Wales (Charity No 295716) and in Scotland (Charity No SC040123). JDRF is registered as a company limited by guarantee, in England and Wales (No 2071638).   |
| Net Income             | The gross income received by the Grantee Institution from the licensing, sale, transfer or other commercial utilisation of any Research results and Arising Intellectual Property, less payments that the Grantee Institution makes to any applicable inventors in accordance to the Grantee Institution policies and less direct, unreimbursed out-of-pocket expenses paid by the Grantee Institution to third parties for patent or licensing any Research result or Arising Intellectual Property. |
| Parties                | JDRF UK, SMF, the Award Holder and the Grantee Institution.   |
| Report                 | The written document presenting any and all information, data and / or findings developed or created, including any Arising Intellectual Property as a result of the Research.  |
| Research               | The research described in the Application and, where the Application relates only to part of a larger project, the Research means that part only.   |
| SMF                    | The Steve Morgan Foundation, a charity registered with the Charity Commission for England and Wales (registered charity number 1087056) whose principal office is The Steve Morgan Foundation, P. O. Box 3517, Chester, CH1 9ET as the Funder of the Award.   |
| Terms                  | The terms and conditions set out in this document.  |

For questions regarding any administrative component of this document, please contact JDRF UK.

## **1. Ethical Oversight**

### **1.1 Human Subjects & Animal Welfare**

#### **1.1.1 Institutional Animal Care and Use Committees and Institutional Review Boards**

All Award Holders (whether working in clinical or laboratory research) are strongly encouraged to work with JDRF UK and the Funder to implement opportunities for the involvement of people with or with a connection to type 1 diabetes; improving research design, recruitment strategy, dissemination of results and research relevance.

The Award Holder, Co-applicants, Collaborators and all staff must ensure all research involving animals is fully compliant with current Home Office legislation.

Research using animals funded by JDRF UK must follow the NC3Rs and cross-funder guidance on Responsibility in the Use of Animals in Bioscience Research.

All researchers are expected to follow the principles and guidelines set out by MRC's Good Research Practice.

The Grantee Institution must ensure that before the Award commences and during the term of the Award, all the necessary legal and regulatory requirements, including any necessary or appropriate ethical approval, in order to conduct the Research are met. This includes obtaining all licences and approvals. The Grantee Institution accepts full responsibility for ensuring that any such approvals are in place at all relevant periods of the Award.

### **1.2 JDRF UK Requirements**

#### **1.2.1 Confidentiality and Data Protection**

As a charity, JDRF UK and SMF have the responsibility to disclose to the public details of the research funded. The lay abstract and reports will be made publicly available.

Information shared and/or acquired as a result of this contract will be kept confidential to the extent that such information is not available in the public domain.

All parties will comply with the Data Protection Act 2018 and any subsequent legislation and guidance.

### **1.3 Conflict of Interest**

In the interest of maintaining objectivity in research, JDRF UK must ensure that its grant processes are free from conflicts of interest. JDRF UK recognises that the Grantee Institution may be involved in a variety of organisations and projects, and may hold financial investments, which may create actual or potential conflicts of interest, or the appearance of a conflict.

The Grantee Institution is required to have established policies about, and safeguards against, conflicts of interest. The Grantee Institution must have protections in place that prevent the Grantee Institution and its employees or consultants/subcontractors from using their positions for personal gain (for themselves, or for

other individuals, friends, business associates, family members, or others), financially or via gifts, favours, or other similar actions. The Grantee Institution is also responsible to ensure that all aspects of JDRF UK's funded research are not influenced by conflicts of interest, financial or otherwise. The Grantee Institution is required to have written guidelines to prevent such conflicts of interest, reflecting applicable institution/organisation policy.

A Grantee Institution that has identified conflicts of interest as they relate to JDRF UK's funded research should report these conflicts of interest, in writing, to its JDRF UK Research Administrator as soon as possible.

#### **1.4 Scientific or Financial Misconduct**

The Grantee Institution is required to have its own policies and procedures for the avoidance and reporting of scientific and financial misconduct and is required to enforce those guidelines (when applicable) to any JDRF UK's funded research. By accepting the Award, the Grantee Institution agrees and acknowledges to JDRF UK and the Funder that it has such established policies and procedures and agrees to abide by them while conducting research or other activities relating to the Award.

The Grantee Institution is required to report any instances of scientific or financial misconduct to JDRF UK and the Funder as soon as it is aware of the misconduct. Should scientific or financial misconduct occur, the Grantee Institution must notify JDRF UK and the Funder, in writing, of the nature of the violation, the corrective actions that will be taken in order to correct the violation, and a timeline in which those corrective actions will be executed. JDRF UK may elect to place the Grantee Institution on administrative probation, may withhold funds, may request the return of funds as deemed appropriate, or may take other corrective action during this time period. If, at the end of the Grantee Institution's designated timeline for taking corrective action, the action has not been taken or does not meet JDRF UK standards, JDRF UK and / or the Funder may elect to terminate the Award or continue other corrective actions, if applicable. In the case of scientific misconduct, if the violation is severe, or if public health, human, or animal welfare requires urgent action, JDRF UK and / or the Funder may elect to immediately terminate the award (see Section 7, below).

An Award Holder's failure to comply with the Grantee Institution's ethical and financial guidelines and/or JDRF UK's guidelines, as defined above, may result in modification of the Terms of the award, payment suspension, administrative probation, or award termination.

#### **1.5 Funding Provider and not Sponsor**

The Grantee Institution acknowledges that JDRF UK and the Funder are providers of certain funding for the research to be performed under an Award and are not sponsors of the Research. The Grantee Institution agrees that it will not make any statement, written or oral, alleging that JDRF UK or the Funder is a sponsor of the Research under the Award.

### **2. Payment**

Payments are made on a milestone basis as set out in the attached Award Letter. The approved project must initiate on the Project Period start date as stated in the Award Letter and conduct of the research plan continue for the period authorised in the Renewal Confirmation. Neither of these activities shall be impacted by receipt of JDRF UK and / or the Funder payment for the JDRF UK Award (funded by SMF). Failure to

comply with this requirement may result in JDRF UK and/or the Funder adopting actions described in Section 7.

### **3. Cost Considerations**

#### **3.1 Cost Principles**

Expenses within each grant year's budget and within the expenditure report must reflect the JDRF UK approved budget for the grant budget period. The grant's expenses must be allowable, allocable and reasonable as per the cost principles appropriate for the Grantee Institution, this document, and/or set forth in a contract, agreement or MOU before Award activation. Funds' expenditure must be allocated appropriately and expenditures in excess of the approved yearly budget are not allowed. Negative balances cannot be carried into future budget periods. All funds exceeding the amount awarded by JDRF UK must be reconciled within the Grantee Institution. Any non-JDRF UK funds spent on a JDRF UK project in excess of the awarded budget amount are not entitled to reimbursement from JDRF UK.

JDRF will only reimburse directly incurred costs relating to the Research. JDRF UK does not pay directly allocated costs or indirect costs (estates or overheads). Indirect costs represent the costs of central and distributed services shared by other activities that are not project-specific e.g. Finance, IT and Human Resources (For more information about fund headings and full economic costings see <https://www.trac.ac.uk/>).

A non-exclusive list of non-allowable costs includes:

- Lobbying: JDRF UK grant funds may not be used for lobbying purposes of any kind.
- Tuition and registration fees
- General office supplies/equipment
- Computers
- Administrative assistance costs
- Financial Analyst, Accountant cost
- Library
- Departmental services
- Rent
- Office telecommunications
- Advertising costs
- Patent applications
- Indirect cost for fee-for services, consultants, and contractors

JDRF UK may alter these cost principles and policies on a case-by-case basis at the discretion of the JDRF UK and the Funder. If so, JDRF UK will promptly inform the Award Holder.

#### **3.2 Direct Costs Guidelines**

Direct Costs are defined as those costs falling within the following JDRF UK budget categories: Salaries & Wages, Stipends, Supplies, Other Costs, Research Allowances, and Travel.

- Salaries and Wages includes wages earned by an employee, and may include benefits, including insurance and retirement plans. JDRF UK and the Funder require the Grantee Institution to have

administrative and financial controls in place to allocate and track salaries and wages in real time across a JDRF UK funded project.

- Stipends are applied for JDRF UK Postdoctoral and Advanced Postdoctoral Fellowships in place of Salary and Wages. Stipend levels are determined based on the fellow's years of postdoctoral experience.
- Supplies are general purpose consumable items that are used on a regular basis and have a shorter life span in use than equipment and machines.
- Other costs might include items that are not consumable but are needed on a regular basis, such as animal purchases and maintenance charges.
- Travel may include any domestic and/or international journeys by an employee related to the project and is limited to 2,000 GBP per year on an award unless otherwise approved by JDRF UK.

### **3.3 Salary and Personnel Guidelines**

Senior/Key personnel are individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested. Key personnel must devote measurable effort to the project whether or not salaries are requested. Measurable effort is considered to be 5% or greater.

### **3.4 Equipment Guidelines**

Equipment costs are generally only allowed to be budgeted and expended in Year 1 of an Award. Equipment is intended for the sole use of the Award Holder, Co-applicants, staff, and any Collaborators listed as personnel on the Award specifically to execute the approved scope of the project unless cost-shared with another funding source.

Title of the equipment purchased with funds from this Award will be vested in the Grantee Institution conducting the Research. The Grantee Institution is explicitly responsible for the maintenance, control, and all associated costs of capital equipment in its custody and control. Use of funds from this Award for costs other than the acquisition of capital equipment as specified in the previous statement is unallowable.

In the event of an approved transfer of an Award to another institution, the equipment necessary for the continuation and success of the project will be transferred to the new Grantee Institution and title vested in the new institution for use by the designated Award Holder and personnel listed on the project. Upon termination of the Award, all equipment purchased with funds from this Award is permanently vested in the Grantee Institution at Award termination.

### **3.5 Contractual Cost Guidelines**

Contractual costs include all subcontract, contract and fee-for-service costs.

### **3.6 Budget Allocation**

Allocation of costs per each budget category must be completed in compliance with the Grantee Institution's internal policies. However, JDRF UK and the Funder reserve the right to request the reallocation of a cost to a particular budget category if deemed appropriate.

## **4. Administrative Requirements**

### **4.1 Change in Research Plan**

Any revision to the approved research plan must be approved by JDRF UK and the Funder personnel responsible for the oversight of the Award. The request must be submitted through RMS360 by an organisational official.

### **4.2 Unexpended Balances**

If, upon submitting the final expenditure report, the Grantee Institution reports unexpended funds that exceed 200 GBP, the Grantee Institution must refund JDRF UK the full unexpended balance.

Please note that the Grantee Institution may not charge JDRF UK a fee to convert / return funds. Refunds are due to JDRF UK within 60 days of the expenditure report due date.

### **4.3 Carry Forwards**

If an unexpended balance remains at the end of a given grant year for a multi-year grant, JDRF UK and the Funder may allow the Grantee Institution to carry forward the funds into the following year. All carry forward requests must be submitted by the Grantee Institution within 90 days after the end of the previous funding period.

#### **4.3.1 Automatic Carry Forward**

For Awards with an approved annual budget of less than or equal to 500,000 GBP, the Grantee Institution may carry forward any unexpended balance that is less than 20% of the approved annual budget. For awards greater than 500,000 GBP in a given budget year, the Grantee Institution may automatically carry forward any unexpended balance that is less than 10% of the approved annual budget. For multi-project grants, the threshold applies to the total grant amount across all sub-projects.

#### **4.3.2 Non-Automatic Carry Forwards**

For unexpended balances in excess of the thresholds described in 4.3.1, the Grantee Institution must formally request to carry forward funds. Approval is subject to the JDRF UK and the Funder prior consent.

### **4.4 No-Cost Extension (NCE)**

For most Awards, the Grantee Institution may request an extension of the final budget period of a JDRF UK's funded project one time for a period of up to 12 months beyond the original expiration date of the project if additional time is needed in order to accomplish the JDRF UK-approved scientific objectives of the project. Funds remaining at the end of the grant period are not sufficient justification to extend the project period. All NCE requests are subject to JDRF UK and the Funder approval.

For the duration of the extension, the Grantee Institution may not ask for additional funds for the project in question. Additionally, the approved scope of the project must not change during the extension period.

JDRF UK encourages the Award Holder and other relevant key personnel to dedicate a significant amount of percent effort to the Award during the no-cost extension. The Grantee Institution may expense salary for key personnel during the no-cost extension. However, the percent effort expended to the Award cannot exceed that which was approved in the final budget year. (See section 4.6 concerning change in percent effort). Furthermore, the Grantee Institution must prioritise non-personnel expenses required to complete the approved Research plan before allocating salary and wages to the Award.

Upon JDRF UK and the Funder approval of the no-cost extension, the Grantee Institution is expected to ensure that all certifications/ethical assurances are up-to-date (if applicable) and that all JDRF UK policies outlined in these Terms and Conditions are followed.

In general, no-cost extensions will not be approved for Postdoctoral Fellowships, Innovative Grants, and High Priority/Short Term Awards. For postdoctoral and advanced postdoctoral fellows, all funds must be expended by the end of the final budget year. Only in situations of a documented and approved leave of absence (LOA) may training fellowships receive no-cost extensions (NCE). See 4.7 for a description of the LOA process.

NCE requests must be submitted to JDRF UK and the Funder no later than 45 business days preceding the end date of an Award (please contact JDRF UK for further detail on applying for a NCE).

#### **4.5 Reallocation of Funds**

The Grantee Institution must seek JDRF UK and the Funder approval to reallocate funds across budget lines.

##### **4.5.1 For Grants less than or equal to 500,000 GBP per year**

JDRF UK and the Funder permit up to 20% of funds to be reallocated per budget line-item categories without prior JDRF UK and the Funder approval. Any reallocation of funds exceeding 20% of budget line-item categories must have prior approval from JDRF UK and the funder.

##### **4.5.2 For Grants greater than 500,000 GBP per year**

JDRF UK and the Funder permit up to 10% of funds to be reallocated per budget line-item categories without prior JDRF UK and the Funder 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 UK and the Funder.

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

The Grantee Institution must submit a written request to JDRF UK and the Funder if the Award Holder 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 UK awards.

JDRF UK and the Funder must approve any alternate arrangement proposed by the Grantee Institution, including any replacement of the Award Holder or key personnel named in the budget. JDRF UK and the



Funder reserve the right to modify the Terms of the Award, suspend payment, or terminate the Award if the change in key personnel is deemed unacceptable.

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

An Award Holder's leave of absence (LOA), including maternity and paternity leave, must be submitted in writing to JDRF UK and the Funder 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 Award Holder, and signature of the Grantee Institution's authorised signing official.

#### **4.8 Transfers**

In the event that the Award Holder transfers to a new institution, a request to change the Grantee Institution must be submitted in writing to JDRF UK and the Funder. JDRF UK and the Funder will consider such a request provided that the original Grantee Institution will relinquish the Award and that the new Grantee Institution will accept the Award and JDRF UK'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 UK's and the Funder'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.

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

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

#### **5.1 Activation**

Following receipt of the Award 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 Awards, a final scientific progress report is required within 3 months of the end of the grant period. Final progress reports are also required for all Awards that have been terminated (initiated either by JDRF UK, the Funder 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.

A Follow Up Report must also be submitted 18 months after the end of the Award. This will help JDRF UK to assess the impact of this award scheme in the longer term and potentially help to develop new schemes.

## **5.4 Additional Progress Reporting**

In addition to the annual and final progress reports, Awards made as part of the Steve Morgan Foundation Type 1 Diabetes Grand Challenge require the Award Holder to submit short progress reports every four months in line with the agreed project milestones. 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 UK and the Funder is to find a cure for Type 1 diabetes and its complications through the support of research. In furtherance of this mission, JDRF UK 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.

Arising Intellectual Property shall vest in and be owned by the Grantee Institution.

The Grantee Institution shall ensure that all persons in receipt of the Award funding or working on an activity funded under the Award (including employees, students, Co-applicants, Collaborators and subcontractors) are employed or retained on terms that vest in the Grantee Institution all Arising Intellectual Property from the Award.

The Grantee Institution shall disclose in writing to JDRF UK and the Funder within 60 days all Arising Intellectual Property that may be of medical or commercial value.

In acknowledgement of JDRF UK's Award (funded by SMF), the Grantee Institution shall pay JDRF UK and SMF a royalty in the aggregate amount of ten percent (10%) of Net Income, up to an aggregate amount equal to five (5) times the funding provided by the Award under which the Arising Intellectual Property was developed.

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

As between (1) JDRF UK and the Funder and (2) 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 an Award provided by JDRF UK and funded by SMF (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.

The Grantee Institution shall require any subcontractor that it engages to conduct research using an Award provided by JDRF UK and the Funder 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.

The Grantee Institution hereby grants to JDRF UK and the Funder 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 UK and the Funder 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 UK and the Funder 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 a JDRF UK Award funded by SMF. 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 a JDRF UK Award funded by SMF.

### **5.6.3 Invention Disclosures**

The Grantee Institution shall disclose to JDRF UK and SMF 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 an Award provided by JDRF UK and funded by SMF (each an "Invention") that are potentially patentable. The Grantee Institution shall make such disclosure by contacting JDRF UK and the Funder. 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 commercialising the Invention, including a list of any potential licensees.

### **5.6.4 Patents**

As between (1) JDRF UK and the Funder and (2) 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 UK and the Funder of such decision, and at JDRF UK's and the Funder'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 UK and the Funder.

The Grantee Institution shall notify JDRF UK and the Funder 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 UK and the Funder from obtaining patent protection for such Invention in such jurisdiction.

## 5.6.5 Commercialisation

### 5.6.5(a) Commercialisation Efforts

Upon the disclosure of a new Invention or generation of any other Research Results, the Grantee Institution shall take appropriate steps to commercialise 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 UK and the Funder determine in good faith, after consulting with the Grantee Institution, that the Grantee Institution has not itself or through one or more licensees diligently pursued commercialisation 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 UK's and / or the Funder's request the Grantee Institution shall meet with JDRF UK and the Funder to discuss a commercialisation plan for the Research Results that is reasonably satisfactory to JDRF UK and the Funder. If the Grantee Institution is unable to commercialise the Research Results within the timeframe specified in the commercialisation plan, then at JDRF UK's and / or the Funder's request the Grantee Institution shall assign, license or otherwise transfer any or all rights in or control of such Research Results to JDRF UK and the Funder, 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 UK and the Funder 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 UK and the Funder with written notification pursuant to Section 5.6.5(b)(1) of this Policy, the Grantee Institution shall initiate consultation with JDRF UK and the Funder 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 UK and the Funder with a draft of the proposed exclusive License. At its discretion, JDRF UK and the Funder 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 UK and the Funder comment in writing, then the Grantee Institution shall respond to JDRF UK's and the Funder's comments in writing. With respect to any decision regarding whether to grant an exclusive License, the Grantee Institution and JDRF UK and the Funder 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 (1) Grantee Institution and (2) JDRF UK and the Funder agree that an exclusive License should be granted if and only if the granting of such exclusive License is reasonably likely to: (i) maximise the positive impact of the subject matter of the License on the health and well-being of Type 1 diabetes patients; (ii) maximise the availability of diagnostic or therapeutic products to Type 1 diabetes patients; and (iii) maximise 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 (1) Grantee Institution and (2) JDRF UK and the Funder 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 non-exclusivity 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 UK and the Funder; Commercialisation by JDRF UK and the Funder**

In the event of an assignment or other transfer to JDRF UK and the Funder of any rights in or control of any Research Results as provided in this Policy, the Grantee Institution shall cooperate with JDRF UK and the Funder (at their 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 UK and the Funder in order to effectuate such transfer. After the effective date of any such transfer, as between the (1) Grantee Institution and (2) JDRF UK and the Funder, JDRF UK and the Funder 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 UK and the Funder commercialise 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 UK and the Funder, JDRF UK and the Funder 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 UK and the Funder and the Grantee Institution. In addition, in the event that JDRF UK's and the Funder'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 UK and the Funder, then the Grantee Institution shall grant to JDRF UK and the Funder 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 commercialise such product, and to the extent that the Grantee Institution has the authority to grant such rights. In the event that JDRF UK's and the Funder'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 the subject of an Award from JDRF UK (funded by SMF), then the Grantee Institution shall reasonably negotiate with JDRF UK and the Funder with respect to any such intellectual property rights that JDRF UK and the Funder would

require in order to commercialise 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 UK's Award (funded by SMF), the Grantee Institution shall pay to JDRF UK and the Funder a royalty in the amount of ten percent (10%) of Net Income, up to an aggregate amount equal to five (5) times the total Award provided by JDRF UK (funded by SMF) 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 utilisation 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 UK and the Funder shall receive 10% of such consideration by a direct grant to JDRF UK and the Funder.

The Grantee Institution shall make all such payments to JDRF UK and the Funder 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 UK and the Funder, upon request, financial information adequate to establish and document the amount of Net Income. JDRF UK and the Funder 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 UK and the Funder shall survive indefinitely after the expiration and/or termination of the Award.

In the event that JDRF UK and / or the Funder 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 UK and the Funder and that are later licensed, sold, or otherwise transferred by the Grantee Institution to a third party for commercialisation, the Grantee Institution shall require such third party, as a condition of such license, sale or other transfer, to reimburse JDRF UK and the Funder for all prior funding of such costs, which shall be in addition to any other amounts required to be paid to JDRF UK and the Funder hereunder.

JDRF UK and the Funder reserve 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 an Award 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 Awards by JDRF UK (funded by SMF). Grantee Institution and/or Company will notify JDRF UK and the Funder at least 60 days in advance if they plan to enter into an equity or financing arrangement related to the Research Results of a JDRF UK Award funded by SMF.

### **5.6.8 Reporting**

The Grantee Institution shall report to JDRF UK and the Funder 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 UK and the Funder any decision to abandon or not pursue patent protection on any Invention. With each such report, the Grantee Institution shall provide JDRF UK and the Funder 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 UK and the Funder shall maintain these documents in confidence as provided in this Policy.

In addition, the Grantee Institution shall submit annual reports to JDRF UK and the Funder describing the status of a JDRF UK Award funded by SMF, 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 commercialise 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 inventions supported by this Award to JDRF UK and the Funder for a period of three [3] years after the expiration and/or termination of the Award. The Grantee Institution agrees to keep JDRF UK and the Funder informed of the status of any Invention disclosure or patent application filed related to an invention supported by the Award. At JDRF UK's and the Funder's request, the Grantee Institution will provide copies of invention disclosures, patent applications, patent allowances and any IP Transfer Agreements. Such information will be for JDRF UK and the Funder's internal purposes only and will be considered confidential. The Grantee Institution's obligation to report to JDRF UK and the Funder shall survive after funding has terminated.

### **5.6.9 Cooperation**

As reasonably requested by JDRF UK and /or the Funder, the Grantee Institution shall from time to time consult with JDRF UK with respect to matters relating to JDRF UK-funded research, including matters relating to the patenting, development and commercialisation of Inventions and other Research Results. For example, if so requested by JDRF UK and the Funder, the Grantee Institution shall discuss with JDRF UK and the Funder the ongoing progress of a JDRF UK Award funded by SMF research, critically assess the results of such research, identify and address any weaknesses or delays in research or commercialisation, and determine when and whether particular research or commercialisation 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 UK and the Funder will consider whether the Grantee Institution has honoured the above Policy.

### **5.7 Publication Requirements**

It is a condition of the award that funding must be acknowledged with the following wording "This work was supported on behalf of the "Steve Morgan Foundation Type 1 Diabetes Grand Challenge" by JDRF UK and SMF (grant number [xxx])" in any scientific presentations, publications or media appearances.

The Award Holder and the Grantee Institution are expected to publish in relevant journals and to provide information to the public on the findings of their JDRF UK Award.

The Award Holder and the Grantee Institution must notify the JDRF UK research team and SMF of any publication relating to a grant awarded under the Steve Morgan Foundation Type 1 diabetes Grand Challenge initiative. Copies of abstracts and journal articles (preprints and reprints) should be provided as soon as accepted.

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

Authors must 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.

Any public announcement (i.e. press release, website posting, public email announcement) must be coordinated with JDRF UK. Please contact the research team at [SMFGrandChallenge@jdrf.org.uk](mailto:SMFGrandChallenge@jdrf.org.uk) for such announcements.

## **5.8 Record Retention**

As per JDRF UK 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 UK Award funded by SMF for a period of at least 7 years.

## **5.9 Auditing**

The control of expenditure to be funded by the Award must be covered by any formal audit arrangements that exist in the Grantee Institution. This should include standards and procedures for maintaining an appropriate anti-fraud and corruption control environment.

JDRF UK and the Funder reserve the right to audit all expenses related to the Award at any time.

As a condition of accepting this Award, the Grantee Institution agrees to maintain books and records documenting the expenditure of the Award.

The Grantee Institution agrees to make these books and records available to JDRF UK and the Funder for review (at JDRF UK's and the Funder's expense) upon request.

## **5.10 Site Visits and Evaluations**

Site visits and evaluations may occur annually for any JDRF UK Award funded by SMF. The Grantee Institution will be notified in advance of an upcoming on-site evaluation and will work with their JDRF UK scientific program manager and/or grant administrator to determine the evaluation structure. Most Awards greater than 500,000 GBP per year may be subjected to a more formal evaluation. In these cases, the JDRF UK 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 UK program personnel will provide the Award Holder with an evaluation



summary statement, to which the Award Holder may be required to respond. Payments for subsequent funding periods may be tied to evaluation results and/or the Award Holder'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://www.clinicaltrials.gov) database (including applicable clinical trials) to ensure information is freely available on JDRF UK Awards (funded by SMF) 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 Clinically Meaningful Outcomes**

The Steering Committee of the T1D Outcomes Program has defined the following outcomes: hypoglycaemia, hyperglycaemia, time-in-range, and diabetic ketoacidosis (DKA). JDRF UK and the Funder 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.

### **6.3 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 UK funded investigators, their staff or volunteer advisors 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 commercialisation claims prior to regulatory approval. However, dissemination of the clinical trial's scientific findings/study results to the scientific and type 1 diabetes community is permissible. Grantees must comply with country-specific regulations in sharing study results with trial participants.

## **7. Termination and Enforcement Actions**

### **7.1 Suspension & Administrative Probation**

JDRF UK and the Funder reserve 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 etc.) and unsatisfactory scientific progress. In addition, JDRF UK and the Funder may place the Award Holder 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 UK and the Funder 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 UK payments for the Award Holder, for any Award
4. Withholding of all JDRF UK payments for the Grantee Institution, for any Award
5. Any combination of the above

An Award Holder under administrative probation will have the opportunity to respond to the probation by sending a rebuttal letter to JDRF UK and the Funder within 15 days of the probation's notification, at which time JDRF UK and the Funder 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 UK and the Funder 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 Variation and Termination**

JDRF UK and SMF reserve the right to amend these Terms and those of the Award Letter.

The Grantee Institution and / or the Award Holder must inform JDRF UK and the Funder immediately of:

- a) any change that might affect their ability to comply with the Contract.
- b) any reasonable suspicion of or actual fraud, corruption or financial impropriety relating to the expenditure of the Award.
- c) any instances of scientific misconduct in relation to the Award and disclose the nature of the misconduct.

JDRF UK and the Funder reserve the right to terminate the Award at its sole discretion on receipt of such notification, unless redress can be made to our satisfaction within 30 days. If termination takes place, unspent funds and any funds not spent in full accord with the Contract must be returned to JDRF UK and the Funder within 30 days.

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

During the grant period, should scientific or grant personnel at JDRF UK or the Funder identify financial, administrative, or programmatic insufficiencies, JDRF UK and the Funder 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 UK and the Funder 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 UK may also require the withdrawal of Award Holder or other key personnel should JDRF UK conclude that the Award Holder and/or other key personnel are no longer competent to perform. Should this be the case, JDRF UK and the Funder may require that the Grantee Institution select a new Award Holder and/or key personnel. All decisions to modify the terms of an award (including withdrawal of Award Holder or other personnel, or other special circumstances or conditions) will be exercised at JDRF UK's and the Funder'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 UK and / or the Funder may administratively recover those funds. JDRF UK and the Funder may require the Grantee Institution to pay back funds, and will specify the terms and timeline for repayment. Additionally, JDRF UK and / or the Funder have the right to set off such amounts against any payment obligations of JDRF UK and / or the Funder to the Grantee Institution. JDRF UK and/or the Funder may take any other actions permitted by law to recover such funds.

#### **8. Grant Appeals Procedures / Rebuttal**

An Award Holder under Administrative Probation or who has been given notice of other JDRF UK and / or the Funder 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 UK. The Grantee Institution must send a rebuttal letter to JDRF UK and the Funder within 15 days of the probation/corrective action notification, at which time JDRF UK and / or the Funder will make a final decision on the suitable course of action and will notify the Grantee Institution as such.