

Award Terms & Conditions

JDRF AWARD NUMBER: X-XXX-XXXX-XXX-X-X

JDRF AWARD TITLE: Title

PRINCIPAL INVESTIGATOR: First Last

GRANTEE INSTITUTION: University of JDRF

The JDRF Terms and Conditions apply to all U.S. and international grantees. JDRF is committed to ensuring that all Board-mandated grants management and oversight requirements are met. To accomplish this goal, JDRF-funded organizations/institutions must comply with the grant terms and conditions outlined here.

By accepting the grant, the Principal Investigator (“PI”) and the Grantee Institution agree 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 conforms to the Terms and Conditions. JDRF allows the Grantee Institution and PI 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 policy and requirements required under these Terms and Conditions.

For questions regarding any administrative component of this document, please contact your JDRF Research Administrator:

JDRF Administrator: First Last

JDRF Contact Information: XXX-XXX-XXXX

xxx@jdrf.org

JDRF Scientific Lead: First Last

JDRF Contact Information: XXX-XXX-XXXX

xxx@jdrf.org

JDRF RMS360

Effective February 2014, JDRF manages all awards through RMS360, a web-based grants management system designed to facilitate the Grantee Institution’s submission of materials from application through closeout.

All documentation associated with an award’s lifecycle must be completed via JDRF’s RMS360. Information regarding RMS360 is available on the [JDRF website](#). Under no circumstance does JDRF accept by email, fax, or mail any reports or documentation as required in the Terms and Conditions described here within.

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1. Ethical Oversight

1.1 Human Subjects & Animal Welfare

1.1.1 Institutional Animal Care and Use Committees and Institutional Review Boards

JDRF follows U.S. National Institutes of Health (NIH) Guidelines for the humane care and use of animals in research and for the use of human subjects in research and requires the Grantee Institution to comply with such Guidelines. According to U.S. Federal law, institutions that use laboratory animals for research or instructional purposes must establish an Institutional Animal Care and Use Committee (IACUC) to oversee and evaluate all aspects of the Grantee Institution's animal care and use programs, facilities, and procedures. Institutions that utilize human subjects in research as defined by the Federal government must establish an Institutional Review Board (IRB) or Ethical Committee (EC). See [NIH's federal guidelines](#) for more information.

1.1.2 JDRF Requirements

The Grantee Institution must comply with all Federal, state and local government regulations regarding the participation of human subjects and the use of animals in research. No part of the Award may be used to support any research involving human subjects or animal studies that does not have the approval of the appropriate EC. All projects with human subjects and/or animal research must have up-to-date ethical approval documentation at all times. For projects involving non-exempt human research, the Grantee Institution bears ultimate responsibility for protecting human subjects under the Award, including human subjects at all participating and consortium sites, and for ensuring that an Assurance approved by the Office for Human Research Protections ("OHRP") and certification of IRB approval have been obtained before human subjects research can be conducted at each collaborating site. Where applicable, JDRF requires the use of a Central IRB to improve the efficiency of conducting multi-site clinical studies. The Grantee Institution must ensure that JDRF receives required, up-to-date documentation for all sites in accordance with the Award milestone schedule and ensure that it is current at the time of submission of award annual renewal materials. Failure to maintain and provide evidence of the necessary IRB and/or IACUC certification or the equivalent would constitute a material breach of these Terms and Conditions and give JDRF the right to enforce actions described in Section 7 including decision to terminate the Award. The [JDRF Administrative Resources](#) describe in detail the documentation required to satisfy the ethical approval requirement.

Any changes to ethical documentation must be submitted to JDRF as approved. In the event that the IRB/EC has determined that the study is exempt, the documentation demonstrating the exempt status must be submitted to JDRF.

For research involving drugs, devices, or biologics regulated by the FDA, then FDA regulations would also apply. In the event that there is discrepancy between FDA and NIH regulations, those that offer greater protection to human subjects should be followed.

The Grantee Institution must notify JDRF **within 24 hours** if there are any regulatory issues, protocol violations or policy changes that impact the ability of the research investigative team to conduct the research as part of this Award.

Foreign Institutions: Ethical approval documentation submitted in a language other than English require a cover letter signed by the Grantee Institution's department head (in English) verifying the content of the form and countersigned by the Grantee Institution's Research Office of record.

1.2 Confidentiality

Most grant materials submitted to JDRF, including quarterly, milestone and annual progress reports, are for internal JDRF use only. **Exceptions include the lay abstract and the annual web progress reports.** As a public charity, JDRF has the responsibility to disclose details to the public regarding the organization's funded portfolio. The lay abstracts and annual web progress reports will be disclosed to the public by JDRF upon award activation. The Grantee Institution and PI should not include any confidential or proprietary information, including intellectual property, in these materials and reports. In the event of a breach of confidentiality, the Grantee Institution and PI assume the responsibility for the premature disclosure. If you have any concerns or questions regarding inclusion of information in a particular report, please contact the applicable JDRF Grant Personnel.

Except with respect to lay abstracts and annual web progress reports, JDRF shall treat as confidential all reports, invention disclosures, and other confidential information received from the Grantee Institution, and shall not disclose any such confidential information to any third party other than JDRF committee members or funding partners without the prior written consent of the Grantee Institution. Any such disclosure by JDRF shall be made subject to appropriate confidentiality restrictions.

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1.3 Conflict of Interest

In the interest of maintaining objectivity in research, JDRF must ensure that its grant processes are free from conflicts of interest. JDRF recognizes that the Grantee Institution may be involved in a variety of organizations 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, favors, or other similar actions. The Grantee Institution is also responsible to ensure that all aspects of JDRF-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/organization policy, along with state and local laws.

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

1.4 Scientific & 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-funded research. By accepting the JDRF award, the Grantee Institution acknowledges that it has such established policies and procedures and agrees to abide by them while conducting research or other activities relating to the JDRF award. In addition, JDRF follows the [NIH's research misconduct guidelines](#), which are defined as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results," and the Grantee Institution agrees to comply with the NIH research misconduct guidelines.

The Grantee Institution is required to report any instances of scientific or financial misconduct to JDRF as soon as it is aware of the misconduct. Should scientific or financial misconduct occur, the Grantee Institution must notify JDRF, 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 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 standards, JDRF 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 may elect to immediately terminate the award (see the Award Termination section, below).

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

1.5 US Economic Sanctions, Anti-Terrorism Laws & Anti-Money Laundering Laws

The Grantee Institution agrees to comply with applicable United States economic sanctions, anti-terrorism laws, and anti-money laundering laws, including, but not limited to, the [USA PATRIOT Act](#), the laws administered by the [United States Treasury Department's Office of Foreign Assets Control](#), [Executive Order 13224](#), and any state or local laws that apply in the jurisdiction in which the Grantee Institution is operating. This provision must be included in all relevant subcontracts/subawards, when applicable.

1.6 Governing Law

The JDRF award and these Terms and Conditions will be governed by New York law. To the extent that a Grantee Institution is required under another state's law to be subject to the laws of that state, and such state laws are in conflict with any provisions of these Terms and Conditions, the Grantee Institution must provide a copy of the applicable state law to the JDRF Research Administration personnel prior to acceptance of the JDRF award, along with a list of the provisions of these Terms and Conditions that are in conflict with such state law. To the extent JDRF agrees to modify or waive any provision of these Terms and Conditions, such modification or waiver will be limited to the extent that the laws applicable to the Grantee Institution are inconsistent with the Terms and Conditions herein. The Grantee Institution must not accept the award until JDRF confirms such modification or waiver in writing. An amendment or waiver of any provision of these Terms and Conditions by JDRF must be in writing to be effective.

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Notwithstanding the foregoing provisions, nothing in these Terms and Conditions is intended to, or should be construed to, conflict with Federal law governing the Grantee Institution, including any Bayh-Dole or NIH obligations that may arise with respect to Inventions (as defined in section 5.6.3 below) resulting from research funded by both JDRF and Federal funds. Federal law shall govern in the event of any inconsistency with these Terms and Conditions.

1.7 Funding Provider and not Sponsor

The Grantee Institution acknowledges that JDRF is solely a provider of certain funding for the research to be performed under an award and is not a sponsor of the research. The Grantee Institution agrees that it will not make any statement, written or oral, alleging that JDRF is a sponsor of the research under the award.

2. Payment

Payments are made in accordance with [JDRF Administrative Resources](#) or as otherwise negotiated per the terms set forth in a contract, agreement or memorandum of understanding (MOU). The approved project must initiate on the Project Period start date as stated in the Award Activation Confirmation and conduct of the research plan continue for the period authorized in the Renewal Confirmation. Neither of these activities shall be impacted by receipt of JDRF payment for the Award. Failure to comply with this requirement may result in JDRF adopting actions described in Section 6.

3. Cost Considerations

3.1 Cost Principles

Expenses within each grant year’s budget and within the expenditure report must reflect the JDRF 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 (domestic institutions, please see chart below), this document, and/or set forth in a contract, agreement or MOU before grant activation. Funds’ expenditure must be allocated appropriately between direct and indirect costs. 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 must be reconciled within the Grantee Institution. Any non-JDRF funds spent on a JDRF project in excess of the awarded budget amount are not entitled to reimbursement from JDRF.

Cost Principles:

OMB Circular A-21 (2 CFR Part 220)	Institutions of Higher Education
OMB Circular A-87 (2 CFR Part 225)	State and Local Governments
OMB Circular A-122 (2 CFR Part 230)	Nonprofit Organizations
45 CFR Part 74, Appendix E	Hospitals
48 CFR Subpart 31.2 (Federal Acquisition Regulations, or FAR)	For-Profit Organizations

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

- Lobbying: JDRF 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
- Rent

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- Office telecommunications
- Advertising costs
- Patent applications
- Indirect cost for fee-for services, consultants, and contractors

**JDRF Postdoctoral Fellows are permitted to purchase a personal computer (up to USD\$2,000) using funds within their research allowance.*

JDRF may alter these cost principles and policies on a case-by-case basis at the discretion of the JDRF International Board of Directors.

3.2 Direct Costs Guidelines

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

- Salaries & Wages includes wages earned by an employee, and may include benefits, including insurance and retirement plans. **Reallocation of percent effort on a project after the end date of an award is not permitted on JDRF awards.** In accordance with OMB A-21, JDRF requires the Grantee Institution to have administrative and financial controls in place to allocate and track salaries and wages in real time across a JDRF-funded project.
- Fringe benefits in the form of employer contributions or expenses for social security, employee insurance, workmen's compensation insurance, tuition or remission of tuition for individual employees are allowable, provided such benefits are granted in accordance with established educational institutional policies, and are distributed to all institutional activities on an equitable basis. Tuition benefits for family members other than the employee are unallowable. Any deductions other than the listed above are not allowable. Car insurance that is not a standard institutional benefit offered to all employees of comparable rank is unallowable.
- Stipends are applied for JDRF Postdoctoral and Advanced Postdoctoral Fellowships in place of Salary & 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.
- Research Allowances are provided for Postdoctoral Fellowships only in the amount of USD\$5,500 per year. These can be used towards travel to scientific meetings, journal subscriptions, books, health insurance costs, etc.
- Travel may include any domestic and/or international journeys by an employee related to the project and is limited to USD\$2,000 per year on an award unless otherwise approved by JDRF.

3.3 Salary and Personnel Guidelines

JDRF follows the U.S. National Institutes of Health (NIH) salary limitation guidelines for Principal Investigators and Post-Doctoral Fellows. JDRF guidelines are adjusted when the new NIH guidelines go into effect. No budget update is needed when there is a change.

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 genuinely considered to be 5% or greater. See [JDRF Administrative Resources](#) for guidelines for key personnel budgeting and information regarding percent effort.

3.4 Indirect Costs Guidelines

Indirect costs are limited to 10% of direct costs. The Grantee Institution may request indirect costs less than 10%. Equipment, subcontract, contractual, and fee-for service costs are not direct costs. In instances where there is a subcontract, the Grantee Institution may budget up to 10% indirect costs on the direct costs to be incurred at the Grantee Institution. The Grantee Institution may not incur any indirect costs off the subcontract costs.

3.4.1 Postdoctoral Fellowships

Indirect costs are not allowable for JDRF Postdoctoral Fellowship awards.

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3.5 Equipment Guidelines

Equipment costs are generally only allowed to be budgeted and expended in Year 1 of an award. Per policy 3.4, JDRF does not permit indirect costs to be charged to the JDRF award on approved equipment purchases. Equipment is intended for the sole use of the PI, Co-PI, 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 JDRF funds will be vested in the Grantee Institution conducting the research project. The Grantee Institution is explicitly responsible for the maintenance, control, and all associated costs of capital equipment in its custody and control. Use of JDRF funds 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 PI and personnel listed on the project. Upon termination of the award, all equipment purchased with JDRF funds is permanently vested in the institution at award termination.

3.6 Contractual Cost Guidelines

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

3.7 Budget Allocation

Allocation of costs per each budget category must be completed in compliance with the Grantee Institution's internal policies. However, JDRF reserves 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 personnel responsible for the oversight of the grant award. The request must be submitted through RMS360 by an organizational official.

4.2 Unexpended Balances

If, upon submitting the final expenditure report, the Grantee Institution reports unexpended funds that exceed \$250 USD, the Grantee Institution must refund JDRF the full unexpended balance. **Please note that the Grantee Institution may not charge JDRF a fee to convert/return funds. Refunds are due to JDRF 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 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. See [JDRF Administrative Resources](#) for detailed instructions of documentation required for carry forward amounts.

4.3.1 Automatic Carry Forward

For awards with an approved annual budget of less than or equal to \$500,000, 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 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 Postdoctoral Fellows and Advanced Postdoctoral Fellows

Postdoctoral fellows may automatically carry forward unexpended funds from the research allowance only. Funds allocated for stipends cannot be carried forward.

4.3.3 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 International Board of Directors.

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4.4 No-Cost Extension (NCE)

For most grants, the Grantee Institution may request an extension of the final budget period of a JDRF-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-approved scientific objectives of the project. **Funds remaining at the end of the grant period are not sufficient justification to extend the project period.**

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 encourages the PI 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 prioritize non-personnel expenses required to complete the approved research plan before allocating salary and wages to the JDRF award.

Upon JDRF 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 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 **NO LATER THAN 45 business days preceding the end date of an award**. See [JDRF Administrative Resources](#) for instructions for applying for an NCE.

4.5 Reallocation of Funds

The Grantee Institution must seek JDRF approval to reallocate funds across budget lines. Instructions for submitting reallocation requests are found within [JDRF Administrative Resources](#).

4.5.1 For Grants less than or equal to \$500,000 (USD) per year

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.

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

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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.

5. Monitoring & Reporting

5.1 Transfers

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 6.1 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 6.1 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 6.1 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 the 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 (as defined below, 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.

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 potentially patentable inventions 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”). 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 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 30 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 responsibly, 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 the 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

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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 gross income 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 patent or licensing any Research Results. 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 after funding has terminated.

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 use commercially reasonable efforts to require such third party, as a condition of such license, sale or other transfer, to reimburse JDRF for all prior funding of such costs.

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.

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 of JDRF grant in question. 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.

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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 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).

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

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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 agree 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 A-133/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 & A-133

U.S. and Canadian organizations/institutions that receive more than \$500,000 per year in U.S. Federal award funds must conduct an independent yearly audit under the guidelines of the OMB A-133 Compliance Supplement. As a component of JDRF's auditing and monitoring practices, the Grantee Institution's A-133 audit report is required on an institutional basis. For international Grantee Institutions, or for U.S./Canadian Grantee Institutions that expend less than \$500,000 per year in U.S. Federal award funds, equivalent yearly audit reports are required.

For a Grantee Institution that does not conduct an independent external audit, an official letter signed by a Grantee Institution official must be submitted instead of the required A-133 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](#).

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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 Managers Shachi Vyas (svyas@jdrf.org) and Mahmoud Hassan (mhassan@jdrf.org) with any questions.

6.4 Communication to Clinical Trial Participants

Clinical trial participants should be made available a lay summary of results from the clinical trial at the time of data presentation to lay or scientific communities. 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. You must comply with your 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 6-month 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

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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 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 6.1 and 6.2, 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 have 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]