



Please note: This is the current version of the Breakthrough T1D Terms and Conditions. The Terms and Conditions that your institution executed can be found within each individual grant in the Research Officer (RO) portal in RMS360.

Breakthrough T1D will not modify these terms at the request of individual institutions. Breakthrough T1D's terms have been approved by our Board of Directors, and we do not have the resources to negotiate separately with the many institutions that receive our support.

Rev. 7/24

Award Terms & Conditions

Breakthrough T1D GRANT KEY: X-XXX-XXXX-XXX-X-X

PROJECT TITLE: Title

PRINCIPAL INVESTIGATOR: First Last

GRANTEE INSTITUTION: University of Breakthrough T1D

The Breakthrough T1D Terms and Conditions apply to all U.S. and international grantees. Breakthrough T1D is committed to ensuring that all Board-mandated grants management and oversight requirements are met. To accomplish this goal, Breakthrough T1D-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 Breakthrough T1D conforms to the Terms and Conditions. The Grantee Institution and PI may 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, Breakthrough T1D policy and requirements required under these Terms and Conditions.

For questions regarding any administrative component of this document, please contact your Breakthrough T1D Research Administrator:

Breakthrough T1D Administrator: First Last

Breakthrough T1D Contact Information: XXX-XXX-XXXX - xxx@breakthrough1d.org

Breakthrough T1D Scientific Lead: First Last

Breakthrough T1D Contact Information: XXX-XXX-XXXX - xxx@breakthrough1d.org

[Breakthrough T1D RMS360](#)

Effective February 2014, Breakthrough T1D 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 Breakthrough T1D's research management system, [Breakthrough T1D RMS360](#). Under no circumstance does Breakthrough T1D 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

Breakthrough T1D follows U.S. National Institutes of Health (NIH) Public Health Service Policy guidelines for the humane care and use of animals in research and the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects in research (45 CFR 46). Breakthrough T1D requires the Grantee Institution to comply with these guidelines, including the recent [Revised Common Rule](#). Applicants are required to comply with all applicable Federal, state, and local laws, regulations, and requirements; when there are differences between local and NIH guidelines we recommend applicants notify Breakthrough T1D. International Grantee Institutions are required to comply with their local regulations and requirements at an equivalent standard of protection as those in the U.S.

According to U.S. Animal Welfare Act, 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 Research Ethics Committee (REC). See Federal guidelines on [animal research](#) and [human subjects research](#) for more information.

1.1.2 Breakthrough T1D 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 grant may be used to support any research involving human subjects or animal studies that does not have appropriate regulatory and/or ethics approvals. All projects with human subjects and/or animal research must be in possession of and provide Breakthrough T1D with up-to-date ethical approval documentation at all times. For projects involving [non-exempt human subjects research](#), the Grantee Institution bears ultimate responsibility for protecting human subjects under the grant. This includes protection of human subjects at all participating sites with oversight by an Office(s) for Human Research Protections ("OHRP"). Appropriate local or central IRB approval(s) must be obtained before human subjects research can be conducted at each collaborating site.

Where applicable, the use of a Central IRB is permitted when conducting single- or multi-site clinical studies. For multi-site or consortium trials, the Grantee Institution must ensure that Breakthrough T1D receives all requisite and up-to-date documentation of regulatory and/or ethics approvals for all sites and in accordance with the grant milestone schedule. The Grantee Institute is required to ensure that documentation remains current at the time of submission of the grant's annual renewal materials. Failure to maintain and provide evidence of the necessary approved IRB, REC, and/or IACUC certification or the equivalent would constitute a material breach of these Terms and Conditions and Breakthrough T1D may take action which may include the utilization of terms under Section 7, Termination and Enforcement actions. The [Breakthrough T1D Grant Handbook](#) describes in detail the documentation required to satisfy the ethical approval requirement.

Any and all changes to regulatory and ethical documentation must be submitted to Breakthrough T1D via RMS360. In the event that the IRB or REC has determined that a study is exempt, the documentation demonstrating the exempt status must be submitted to Breakthrough T1D.

For research involving investigational or approved drugs, devices, or biologics additional regulatory requirements by the FDA or equivalent global bodies may be required. In the event that there is discrepancy between regulations, those that offer greater protection to human subjects should be followed. The Grantee Institution must notify Breakthrough T1D **within 24 hours** of any regulatory issues, serious protocol violations, safety events, or policy changes that meet stopping guidelines or otherwise impact the ability of the research investigative team to conduct the research as part of this grant.

Foreign Institutions: Ethical approval documentation submitted in a language other than English requires either a fully translated document or 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

Grant materials submitted to Breakthrough T1D, including quarterly, milestone and annual progress reports, are for internal Breakthrough T1D use only, **with select exceptions, including the lay abstract and the annual web progress reports**. As a public charity, Breakthrough T1D has the responsibility to disclose information to the public regarding the organization's funded portfolio. The lay abstracts and annual web progress reports will begin to be disclosed to the public by Breakthrough T1D upon grant activation. The Grantee Institution and PI should not include any confidential or proprietary information, including intellectual property, in these application and report sections. In the event of a breach of confidentiality, the Grantee Institution and PI assume the responsibility for the premature disclosure. If PI or Grantee Institution have any concerns or questions regarding inclusion of information in a particular report, please contact the applicable Breakthrough T1D Grant Personnel.

Except with respect to lay abstracts and annual web progress reports, Breakthrough T1D 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 Breakthrough T1D committee members or funding partners who are under appropriate confidentiality agreements, without the prior written consent of the Grantee Institution. Any such disclosure by Breakthrough T1D shall be made only with appropriate confidentiality terms in place.

1.3 Conflict of Interest

Breakthrough T1D recognizes that the Grantee Institution may be involved with 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 to safeguard against conflicts of interest. The Grantee Institution must have protections in place that prevent the Grantee Institution and its staff (employees, including but not limited to investigators, post-doctoral fellows, students and research officers), contractors, subcontractors, and third-party collaborators under an agreement for the purpose of the research project (collectively "Grantee Institution Stakeholders") 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 Breakthrough T1D-funded research are not influenced by conflicts of interest, financial or otherwise. The Grantee Institution is required to have written guidelines for their staff and to enforce its guidelines to prevent such conflicts of interest, reflecting applicable institution/organization policies, along with state and local laws; equivalent protections are expected for subcontractors and third-party collaborators receiving Breakthrough T1D funds under the grant.

A Grantee Institution that has identified conflicts of interest as they relate to Breakthrough T1D-funded research should report these conflicts of interest, in writing, to its Breakthrough T1D 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 Breakthrough T1D-funded research. By accepting the Breakthrough T1D grant, the Grantee Institution warrants that such policies and procedures are established and will be abided by in the course of the performance of research or other activities relating to the Breakthrough T1D grant. In addition, the Grantee Institution agrees to comply with the NIH research misconduct [guidelines](#), fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

The Grantee Institution is required to report any instances of scientific or financial misconduct to Breakthrough T1D as soon as it is aware of the misconduct. Should scientific or financial misconduct occur, the Grantee Institution must notify Breakthrough T1D, 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. Breakthrough T1D 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 Breakthrough T1D standards, Breakthrough T1D may elect to terminate the grant 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, Breakthrough T1D may elect to immediately terminate the award (see Section 7, below).

If a Grantee Institution Stakeholder fails to comply with the Grantee Institution's ethical and financial guidelines and/or Breakthrough T1D's guidelines, as defined above, Breakthrough T1D may take action including but not limited to the modification of the terms of the grant, payment suspension, administrative probation, or grant termination (see Section 7).

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. The Grantee Institution or PI must not share any of the grant award information (requirements, data, results, etc.) with a Sanctioned Party or Embargo Country as listed in the Office of Foreign Assets Control sanction lists. This provision must be included by the Grantee Institution in all relevant subcontracts or subawards, when applicable.

1.6 Governing Law

The Breakthrough T1D grant, and these Terms and Conditions will be governed by the laws of the State of New York. 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 conflict with any provisions of these Terms and Conditions, the Grantee Institution may request changes to the provisions of these Terms and Conditions that are in conflict with such state law. To the extent Breakthrough T1D 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 grant until Breakthrough T1D confirms such modification or waiver in writing. An amendment or waiver of any provision of

these Terms and Conditions by Breakthrough T1D must be in writing to be effective.

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 Breakthrough T1D 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 Breakthrough T1D is solely a provider of certain funding for the research to be performed under a grant and is not a sponsor of the research. The Grantee Institution agrees that it will not make any statement, written or oral, alleging that Breakthrough T1D is a sponsor of the research under the grant.

2. Payment

Payments will be made in accordance with the Administrative Resources in the [Breakthrough T1D Grant Handbook](#). The approved project must initiate on the Project Period start date as stated in the grant Activation Confirmation and conduct of the research plan continue for the period authorized in the Renewal Confirmation, as applicable. Neither of these activities shall be impacted by receipt of Breakthrough T1D payment for the grant. Failure to comply with this requirement may result in Breakthrough T1D 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 Breakthrough T1D 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 grant activation. Funds' expenditure must be allocated appropriately between direct and indirect costs as described below in Section 3.4. 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 Breakthrough T1D must be reconciled within the Grantee Institution. Any non-Breakthrough T1D funds spent on a Breakthrough T1D project in excess of the awarded budget amount are not entitled to reimbursement from Breakthrough T1D.

Non-allowable costs include but are not limited to the following:

- Lobbying: Breakthrough T1D grant funds may not be used for lobbying purposes of any kind
- Tuition and registration fees, except as permitted as a fringe benefit per Section 3.2, below
- General office supplies/equipment
- Computers*
- Administrative assistance costs
- Financial Analyst, Accountant cost
- Rent
- Office telecommunications
- Advertising costs
- Patent applications
- Indirect costs for fee-for services, consultants, and contractors
- Data repository technology costs (such as monthly software subscription)

**Breakthrough T1D Postdoctoral Fellows are permitted to purchase a personal computer (up to USD\$2,000) using funds within their research allowance.*

Breakthrough T1D may alter these cost principles and policies on a case-by-case basis at the discretion of Breakthrough T1D. If so, Breakthrough T1D will promptly inform the grantee.

3.2 Direct Costs Guidelines

Direct Costs are defined as those costs falling within the following Breakthrough T1D budget categories: Salaries & Wages, Stipends, Supplies, Other Costs, Equipment and Travel.

- Salaries & Wages includes wages earned by an employee, and may include benefits, including insurance and retirement plans. Breakthrough T1D requires the Grantee Institution to have administrative and financial controls in place to allocate and track salaries and wages in real time across a Breakthrough T1D-funded project.
- Fringe benefits in the form of employer contributions or expenses for social security, employee insurance, workers' 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 Breakthrough T1D 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. Other costs should also include the cost of making publications completely open access, whenever possible (see 5.8).
- Salary and fringe for a statistician or other staff responsible for cleaning and entering data into the public repository, to comply with Breakthrough T1D's Data Sharing requirement (see 5.9), may be included as Direct Costs.
- 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 a grant unless otherwise approved by Breakthrough T1D.

3.3 Salary and Personnel Guidelines

Breakthrough T1D follows the U.S. National Institutes of Health (NIH) salary limitation guidelines for Principal Investigators and Post-Doctoral Fellows. Breakthrough T1D 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 considered to be 5% or greater. See the Administrative Resources in the [Breakthrough T1D Grant Handbook](#) 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 eligible for inclusion in calculating indirect costs. In instances where there is a subcontract, the Subcontract Institution may also budget up to 10% of their direct costs to indirect costs. The Grantee Institution may not incur any indirect costs off the subcontract costs.

3.4.1 Postdoctoral Fellowships

Indirect costs are not allowable for Breakthrough T1D Postdoctoral Fellowship or Advanced Postdoctoral Fellowship grants.

3.5 Equipment Guidelines

Equipment costs are generally only allowed to be budgeted and expended in Year 1 of a grant. Per Section 3.4, Breakthrough T1D does not permit indirect costs to be charged to the Breakthrough T1D grant 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 grant specifically to execute the approved scope of the project unless cost-shared with another funding source.

Title of the equipment purchased with Breakthrough T1D funds will be vested in the Grantee Institution conducting the research project.

The Grantee Institution is explicitly responsible for the maintenance, control, and training cybersecurity and insider threat controls and all associated costs of capital equipment in its custody and control. Use of Breakthrough T1D funds for costs other than the acquisition of capital equipment as specified in the previous statement is unallowable.

Upon termination of the award, all equipment purchased with Breakthrough T1D funds is permanently vested in the institution at grant termination. In the event of a Breakthrough-T1D-approved transfer of a grant 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 Breakthrough T1D funds is permanently vested in the institution at grant termination.

3.6 Budget Allocation

Allocation of costs per each budget category must be completed in compliance with the Grantee Institution's internal policies. However, Breakthrough T1D 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 Breakthrough T1D personnel responsible for the oversight of the grant. 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 Breakthrough T1D the full unexpended balance. **Please note that the**

Grantee Institution may not charge Breakthrough T1D a fee to convert/return funds. Refunds are due to Breakthrough T1D 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, Breakthrough T1D 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. The Administrative Resources in the [Breakthrough T1D Grant Handbook](#) for detailed instructions of documentation required for carry forward amounts.

4.3.1 Automatic Carry Forward

For grants 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 grants 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 and is subject to the prior approval of Breakthrough T1D.

4.4 No-Cost Extension (NCE)

For most grants, the Grantee Institution may request an extension of the final budget period of a Breakthrough T1D-funded grant beyond the original expiration date of the grant if additional time is needed in order to accomplish the Breakthrough T1D-approved scientific objectives of the grant. **Funds remaining at the end of the grant period are not sufficient justification to extend the project period.** All NCE requests are subject to Breakthrough T1D 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.

Breakthrough T1D encourages the PI and other relevant key personnel to dedicate a significant amount of percent effort to the grant during the no-cost extension. The Grantee Institution may expense salary for Key Personnel during the no-cost extension. However, the percent effort expensed to the grant cannot exceed that which was approved in the final budget year. (See 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 Breakthrough T1D grant.

Upon Breakthrough T1D 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 Breakthrough T1D 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 grants. For postdoctoral and advanced postdoctoral fellows, all funds must be expended by

the end of the final budget year. An exception to the above may be made for training fellowships only in situations of a documented and approved leave of absence (LOA). See 4.7 for a description of the LOA process.

NCE requests must be submitted to **Breakthrough T1D NO LATER THAN 45 business days preceding the end date of a grant**. See the Administrative Resources in the [Breakthrough T1D Grant Handbook](#) for instructions for applying for an NCE.

4.5 Reallocation of Funds

The Grantee Institution must seek Breakthrough T1D approval to reallocate funds across budget lines. Instructions for submitting reallocation requests are found within Breakthrough T1D Administrative Resources.

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

Breakthrough T1D permits up to 20% of funds to be reallocated per budget line-item categories without prior Breakthrough T1D approval. Any reallocation of funds exceeding 20% of budget line-item categories must have prior approval from Breakthrough T1D.

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

Breakthrough T1D permits up to 10% of funds to be reallocated per budget line-item categories without prior Breakthrough T1D 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 Breakthrough T1D.

4.6 Changes in Percent Effort for Key Personnel

The Grantee Institution must submit a written request to Breakthrough T1D 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 supersedes the terms under section 4.5. Reallocation of percent effort on a project after the end date of a grant is not permitted on Breakthrough T1D grants.

Breakthrough T1D must approve in writing any alternate arrangement proposed by the Grantee Institution, including any replacement of the PI or key personnel named in the budget. Breakthrough T1D reserves the right to modify the terms of the award, suspend payment, or terminate the grant if the change in key personnel is deemed unacceptable.

Please see the Administrative Resources in the [Breakthrough T1D Grant Handbook](#) for further requirements on changes that may impact the approved budget.

4.7 Leave of Absence

A PI's leave of absence (LOA), including maternity and paternity leave, must be submitted in writing to Breakthrough T1D within 30 days of the start date of the LOA and is subject to the written approval of Breakthrough T1D. The LOA must include an appropriate justification for the leave of absence, the start and end dates of the LOA, the signature of the PI, and signature of the Grantee Institution's authorized signing official.

4.8 Transfers

In the event that the PI transfers to a new institution, a request to change the grantee institution must be submitted in writing to Breakthrough T1D and is subject to the prior written approval of Breakthrough T1D. Breakthrough T1D 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 these 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 Breakthrough T1D'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 the Administrative Resources in the [Breakthrough T1D Grant Handbook](#) for specific procedures.

Except as provided in Section 4.8, the Grantee Institution may not assign its rights or responsibilities under the grant, in whole or in part.

Breakthrough T1D Postdoctoral Fellowship and Advanced Postdoctoral Fellowship recipients must retain the same Mentor for the duration of their Breakthrough T1D. Training grant recipients may only transfer institutions if their Mentor is also transferring to the same institution.

5. Monitoring & Reporting

5.1 Activation

Following receipt of the funding letter, the Grantee Institution shall complete and submit activation materials. Materials are due between 1 to 2 months in advance of the anticipated grant start date. Any exception to this timeline will be made at Breakthrough T1D's discretion.

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 with 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 Breakthrough T1D 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 with this requirement.

5.4 Additional Progress Reporting

In addition to the annual and final progress reports, certain Breakthrough T1D awards may require the Grantee Institution to file progress reports more frequently. If reporting is required at a cadence more frequent than annually, the reporting frequency will be clearly outlined in the funding letter for the individual grant and/or via official correspondence regarding changes to the terms during the life of the grant. See 7.1 for noncompliance with this requirement.

5.4.1 Evaluations

Evaluations may occur during the term of any Breakthrough T1D grant at the discretion of Breakthrough T1D staff. The Grantee Institution will be notified in advance of an upcoming virtual, on-site or hybrid evaluation and will work with Breakthrough T1D staff to determine the evaluation structure. At the end of an evaluation, Breakthrough T1D program personnel may provide the PI with a written summary, 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.

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

Breakthrough T1D funds research in furtherance of its mission to improve the lives of every person affected by Type 1 diabetes (T1D) by accelerating progress on the most promising opportunities for curing, better treating, and preventing the disease. The policy under this Section 5.6 on intellectual property, commercialization, and royalties (the "IP Policy") applies to all Grantee Institutions that receive funding from Breakthrough T1D. By accepting funding from Breakthrough T1D, the Grantee Institution agrees that it is bound by all terms and conditions specified in this IP Policy.

5.6.1 Intellectual Property Rights in the Research Results

As between Breakthrough T1D and the Grantee Institution, the Grantee Institution will own all right, title and interest, including to the extent applicable, all patent, copyright, trademark, and other legal rights, in and to all Inventions (whether or not patentable), products of the mind, tools, scientific discoveries, technological advances, compilations, computer software, printed materials and other works of authorship created, made, conceived or reduced to practice by the Grantee Institution or any of its investigators in the course of conducting research using funding provided by Breakthrough T1D (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 IP 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 Breakthrough T1D to agree to be bound by this IP Policy to the same extent as the Grantee Institution is bound. The Grantee Institution shall provide a copy of this IP Policy to all such subcontractors.

The Grantee Institution hereby grants to Breakthrough T1D 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. Breakthrough T1D 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. Breakthrough T1D 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 IP Policy does not apply to any patents, copyrights, trademarks, or other intellectual property of the Grantee Institution that were not developed under Breakthrough T1D funding, during the period of Breakthrough T1D funding. Unless agreed to otherwise in writing, this IP Policy does not apply to any patents, copyrights, trademarks, or other intellectual property owned by third parties and not developed under Breakthrough T1D funding.

5.6.3 Invention Disclosures

The Grantee Institution shall disclose to Breakthrough T1D within 60 days all Inventions (including without limitation any device, process, method, composition or system) that are conceived or first actually reduced to practice by the Grantee Institution or any of its investigators during the course of carrying out any research using funding provided by Breakthrough T1D that are potentially patentable. Invention(s) shall mean any device,

process, method, composition, or system that is conceived, first actually reduced to practice, or further developed by the Grantee Institution or any of its Investigators during the course of conducting any research using funding provided by Breakthrough T1D. The Grantee Institution shall make such disclosure via Breakthrough T1D'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. A Technology Transfer Office contact must be provided at the time of grant activation.

5.6.4 Patents

As between Breakthrough T1D 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 Breakthrough T1D of such decision, and at Breakthrough T1D'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 Breakthrough T1D.

The Grantee Institution shall notify Breakthrough T1D 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 Breakthrough T1D from obtaining patent protection for such Invention in such jurisdiction.

5.6.5 Commercialization

5.6.5(a) Commercialization Efforts

Upon the disclosure of a new Invention or generation of any other Research Results, the Grantee Institution shall take appropriate steps to commercialize such Research Results in a timely fashion, either itself or through one or more licensees, in the field of diagnosing, curing, treating, and/or preventing Type 1 diabetes and its complications. If Breakthrough T1D 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 Breakthrough T1D's request the Grantee Institution shall meet with Breakthrough T1D to discuss a commercialization plan for the Research Results. If the Grantee Institution is unable to commercialize the Research Results within the timeframe specified in the commercialization plan, then at Breakthrough T1D's request the Grantee Institution shall assign, license or otherwise transfer any or all rights in or control of such Research Results to Breakthrough T1D, 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 Breakthrough T1D 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. The Grantee Institution shall notify Breakthrough T1D whenever the Grantee Institution is planning to grant an exclusive License of any Research Results generated from a Breakthrough T1D grant. The notice shall be in writing pursuant to Section 5.6.5(b)(1) of this IP Policy. The Grantee Institution shall supply Breakthrough T1D with a draft of the proposed exclusive License and allow Breakthrough T1D review and provide comments before anyone else. At its discretion, Breakthrough T1D 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 Breakthrough T1D comments in writing, then the Grantee Institution shall respond to Breakthrough T1D's comments in writing. With respect to any decision regarding whether to grant an exclusive License, the Grantee Institution and Breakthrough T1D 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 IP Policy. Any exclusive License as described in this Section 5.6.5(b) shall be subject to Section 5.6.1 of this IP Policy.

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

(a) Basic Principles and Guidelines. The Grantee Institution and Breakthrough T1D agree that an exclusive License should be granted by Grantee Institution 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 IP Policy, the Grantee Institution and Breakthrough T1D 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 Breakthrough T1D; Commercialization by Breakthrough T1D

In the event of an assignment or other transfer to Breakthrough T1D of any rights in or control of any Research Results as provided in this IP Policy, the Grantee Institution shall cooperate with Breakthrough T1D (at Breakthrough T1D'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 Breakthrough T1D in order to effectuate such transfer. After the effective date of any such transfer, as between the Grantee Institution and Breakthrough T1D, Breakthrough T1D 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 Breakthrough T1D 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 Breakthrough T1D, Breakthrough T1D 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 Breakthrough T1D

and the Grantee Institution. In addition, in the event that Breakthrough T1D'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 Breakthrough T1D, then the Grantee Institution shall grant to Breakthrough T1D 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 Breakthrough T1D'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 Breakthrough T1D, then the Grantee Institution shall reasonably negotiate with Breakthrough T1D with respect to any such intellectual property rights that Breakthrough T1D 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

The Grantee Institution shall pay to Breakthrough T1D 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 Breakthrough T1D (the "Royalty Cap") to the Grantee Institution in connection with the grant under which the applicable Research Results were developed. "Net Income" shall mean all revenues and other consideration (including equity) received by the Grantee Institution from the licensing, sale, transfer or other commercial utilization of any Research Results, less payments that the Grantee Institution makes to any applicable inventors in accordance with the Grantee Institution's policies and less direct, unreimbursed out-of-pocket expenses paid by the Grantee Institution to third parties for patenting or licensing any Research Results. If the Grantee Institution receives an equity interest, including without limitation options, warrants, convertible securities or other similar rights, agreements, arrangements or commitments, or any other right to invest or receive an economic interest in a company (including, but not only, companies founded through the Grantee Institution) in connection with the licensing or other commercial exploitation of the Research Results, in lieu of or in addition to revenue, Breakthrough T1D shall receive 10% of such consideration by direct payment(s) to Breakthrough T1D and such payments will count toward the Royalty Cap.

The Grantee Institution shall make all such payments to Breakthrough T1D 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 Breakthrough T1D, upon request, financial information adequate to establish and document the amount of Net Income. Breakthrough T1D 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 Breakthrough T1D shall survive indefinitely after the expiration and/or termination of the Breakthrough T1D grant.

In the event that Breakthrough T1D has funded the patent costs of any Invention or intellectual property costs of any other Research Results that are not assigned or transferred to Breakthrough T1D and that are later licensed, sold, or otherwise transferred by the Grantee Institution to a third party for commercialization, the Grantee Institution shall require such third party, as a condition of such license, sale or other transfer, to reimburse Breakthrough T1D for all prior funding of such costs, which shall be in addition to any other amounts required to be paid to Breakthrough T1D hereunder.

Breakthrough T1D reserves the right, at the option of the Grantee Institution, to participate in future equity/financing opportunities, in which the Grantee Institution has reserved a similar right, with companies founded involving IP or technology developed as a result of Breakthrough T1D funding and/or licensed or transferred to another entity. This includes companies formed by or incubated at the Grantee Institution or independent of the Grantee Institution, whose work stems from or builds on research funded by Breakthrough T1D. Grantee Institution and/or Company will notify Breakthrough T1D at least 60 days in advance if they plan to enter into an equity or financing arrangement related to the Research Results of Breakthrough T1D funding.

5.6.8 Reporting

The Grantee Institution shall report to Breakthrough T1D 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 Breakthrough T1D any decision to abandon or not pursue patent protection on any Invention. With each such report, the Grantee Institution shall provide Breakthrough T1D 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. Breakthrough T1D shall maintain these documents in confidence as provided in this IP Policy.

In addition, the Grantee Institution shall submit annual reports to Breakthrough T1D describing the status of Breakthrough T1D-funded research, the Research Results (including a description of any intellectual property rights other than Inventions that have been developed), the Grantee Institution's efforts to seek patent protection for, develop and commercialize Inventions and other Research Results, and, if applicable, setting forth the Net Income for such year. Such reports shall include the status of such development, the names of current or potential licensees, the relevant terms of any licenses that are in negotiation or have been executed granting any third party the right to use or practice any Inventions or other Research Results, and the receipt of any royalties and other consideration under such licenses. This requirement does not supersede notification requirements outlined in 5.6.5(b) and 5.6.7.

The Grantee Institution shall report Invention disclosures, patent applications, patent allowances and/or the execution of IP Transfer Agreements (as stated above) related to Breakthrough T1D supported Inventions to Breakthrough T1D for a period of three (3) years after the expiration and/or termination of the Breakthrough T1D grant. The Grantee Institution shall keep Breakthrough T1D informed of the status of any Invention disclosure or patent application filed related to a Breakthrough T1D supported Invention. At Breakthrough T1D's request, the Grantee Institution will provide Breakthrough T1D with copies of Invention disclosures, patent applications, patent allowances and any IP Transfer Agreements. Such information will be for Breakthrough T1D-internal purposes only and will be considered confidential. All reports shall be submitted via Breakthrough T1D's RMS360.

5.6.9 Cooperation

The Grantee Institution shall from time to time consult with Breakthrough T1D with respect to matters relating to Breakthrough T1D-funded research, including matters relating to the patenting, development and commercialization of Inventions and other Research Results, upon Breakthrough T1D's request. For example, if requested by Breakthrough T1D, the Grantee Institution shall discuss with Breakthrough T1D the ongoing progress of Breakthrough T1D-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.

Breakthrough T1D will consider whether the Grantee Institution has honored the above IP Policy in making decisions whether to continue ongoing grants or whether to award additional grants to a PI or their institution.

5.7 Publication Requirements

The Grantee Institution will publish all positive or negative results in relevant scientific, health, or other academic journals and provide information to the public on objectives, methodology, and findings resulting from their Breakthrough T1D-supported research activities. The Grantee Institution must notify Breakthrough T1D Grant Personnel of any publications relating to Breakthrough T1D-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.

During and after the term of the grant, the Grantee Institution shall submit all full-length peer-reviewed publications resulting from Breakthrough T1D funding to Breakthrough T1D prior to the publication date. Breakthrough T1D will honor all embargos.

Grantee Institution must acknowledge Breakthrough T1D funding preferably with inclusion of the Breakthrough T1D Grant Key(s).

5.8 Public Access Policy

Breakthrough T1D expects funded PIs to publish their findings in peer-reviewed journals. PIs are encouraged to further share the results or findings of their studies at relevant conferences and meetings. It is a condition of Breakthrough T1D funding that all peer-reviewed articles supported in whole or in part by its grant be made available in the PubMed Central online archive in accordance with the following conditions:

- Whenever possible, 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.
- Manuscripts in full are required to be completely open access whenever possible or allowed by the journal. Breakthrough T1D funds may be used to cover cost requirements of journals to make publications open access (see 3.2).
- An author must acknowledge Breakthrough T1D support in every article arising from such funding. The acknowledgement statement must include the applicable Breakthrough T1D Grant Key number. This will enable Breakthrough T1D to link the published outputs of research to the support it has provided.

Resources regarding Breakthrough T1D's public access policy can be found under the Administrative Resources in the [Breakthrough T1D Grant Handbook](#).

5.9 Data Sharing

For all grants awarded on or after July 1, 2024 (2025 grant keys and later), investigators are required to make any data that is needed for independent verification of research results freely and publicly available in a data repository by the end of the funding period. Grantees whose grants were awarded on or before June 30, 2024 (2024 grant keys and before) are not required, but are encouraged, to make their data publicly available.

PI's may use a repository of their choice and will be asked to provide the link to their saved data in the final progress report. Grantees are welcome to utilize Breakthrough T1D's Figshare platform via the Health Research Alliance for this purpose, at no cost (for more information see the Administrative Resources in the [Breakthrough T1D Grant Handbook](#)).

Costs of compliance with the data sharing requirement may be allocated as direct costs during the project period, within the parameters described in section 3.2.

Exceptions to the data sharing requirement include Postdoctoral and Advanced Postdoctoral Fellowships, Transition Awards, IDDPs, and certain partnership awards. Selected RFAs may also be exempt as indicated in RFA guidelines, if applicable. Individual exceptions may be requested at the time of grant application.

5.10 Public Announcements

Any public announcement, including but not limited to press releases, website postings, public email announcements and social media that utilizes Breakthrough T1D's name, brand, logo, or other trademarks must be coordinated with Breakthrough T1D and any related international affiliate office ahead of public release. Please contact the Breakthrough T1D Public Relations and Communications team regarding such announcements (e-mail: media@breakthrough1d.org), and, as appropriate, the affiliate at the location of the grant:

Australia: info@jdrf.org.au

Canada: general@jdrf.ca

Israel: office@jdrf.org.il

Netherlands: info@jdrf.nl

United Kingdom: info@jdrf.org.uk

5.11 Record Retention

As per Breakthrough T1D 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 Breakthrough T1D grant for a period of at least 7 years.

5.12 Auditing

Breakthrough T1D reserves the right to audit all expenses related to Breakthrough T1D awards at any time. As a condition of accepting this grant, the Grantee Institution agrees to maintain books and records documenting the expenditure of Breakthrough T1D's grant funds in accordance with customary accounting procedures. The Grantee Institution further agrees to make these books and records available to Breakthrough T1D for review (at Breakthrough T1D's expense) upon request.

Breakthrough T1D may audit grant expenses in order to receive assurance of the following:

1. The Grantee Institution is complying with Breakthrough T1D 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 Breakthrough T1D-funded project (either based on audit summaries or via Breakthrough T1D review of general ledger, when a general ledger is requested), Breakthrough T1D 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.

5.12.1 Independent Audit Reports

U.S. and Canadian organizations/institutions that expend more than \$750,000 per year in U.S. Federal award funds must conduct an independent yearly audit. Breakthrough T1D reserves the right to review the Grantee Institution's audit report upon request. For international Grantee Institutions, or for U.S./Canadian Grantee Institutions that expend less than \$750,000 per year in U.S. Federal award funds, equivalent yearly audit reports would suffice. For a Grantee Institution that does not conduct an independent external audit, an official letter signed by a Grantee Institution official may be submitted instead of the audit report. The letter must state that

the Grantee Institution has financial and operational internal controls in place to successfully manage the Breakthrough T1D grant.

6. Clinical Trials

6.1 Public Trials Registry

Grantee Institution is required to register, update, and report results for all applicable clinical research trials and studies to the [Clinicaltrials.gov](https://clinicaltrials.gov) database. A trial should only be registered and listed once. Database registration serves to inform potential subjects of active and ongoing trials, as well as ensuring that information on Breakthrough T1D funded trials is publicly available. The issued National Clinical Trial Number (NCT#) must be added to the grant record in RMS360.

Breakthrough T1D recommends Grantee Institution to register at or before the time of first patient enrollment. Although the HHS Final Rule (42 CFR 11) requires that registration occur no later than 21 calendar days after enrollment of the first participant, Grantee Institutions should be aware that: (a) many institutions require an NCT number before final IRB approval is issued, and (b) the International Committee of Medical Journal Editors (ICMJE) requires, and recommends that all medical journal editors require, registration of clinical trials in a public trials registry at or before the time of first patient enrollment as a condition of consideration for publication. Breakthrough T1D recommends Grantee Institution to register at or before the time of first patient enrollment.

International Grantee Institutions may also be required to demonstrate to Breakthrough T1D that a trial is also registered in relevant non-US databases including but not limited to EurodaCT and CTIS, as applicable.

As noted above in Section 1.7, Breakthrough T1D is a funding provider and not a sponsor of the research.

6.2 Antidote Bridge

Breakthrough T1D encourages Grantee Institution to register all non-exempt human subjects research to the [Antidote Bridge platform](#). Antidote Bridge hosts Breakthrough T1D's Clinical Trials Connection (CTC) program which provides people with an interest in participating in research with information about ongoing T1D clinical trials.

6.3 Clinically Meaningful Outcomes

Breakthrough T1D requires that all funded clinical studies include clearly defined, up-to-date based on current literature, and clinically meaningful outcome measures.

6.4 Communication to Clinical Trial Participants

Grantee Institution investigators and staff shall not promote or advertise in any context through the 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. Further guidance can be found under 21 CFR 312 and 21 CFR 81.

Dissemination of a clinical trial's scientific findings or study results to the T1D scientific and lay communities, and particularly to clinical trial participants, is permissible and encouraged. Grantees must comply with all country-specific regulations for appropriate sharing of study results with trial participants.

7. Termination and Enforcement Actions

7.1 Suspension & Administrative Probation

Breakthrough T1D reserves the right to withhold grant payments on a grant 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, including but not limited to the reports required in Sections 1 and 5 of these Terms and Conditions, unsatisfactory scientific progress (including but not limited to: unreasonably prolonged and/or unexplained and unresolved delays in meeting project milestones), and scientific or financial misconduct as described in Section 1.4. In addition, Breakthrough T1D may place the PI and/or 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. Breakthrough T1D 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 a payment reimbursement schedule
3. Withholding of all Breakthrough T1D payments for the PI, for any Breakthrough T1D grant
4. Withholding of all Breakthrough T1D payments for the Grantee Institution, for any Breakthrough T1D grant
5. Any combination of the above

A PI under administrative probation will have the opportunity to respond to the probation (see Appeals Procedures, below) by sending a rebuttal letter to Breakthrough T1D within 15 days of the probation notice, at which time Breakthrough T1D will make a final decision on the suitable course of action. Payments will be reinstated when all outstanding documentation has been processed and approved by Breakthrough T1D and/or all required corrective measures have been taken and documented. (It is strongly suggested that the Grantee Institution contact Breakthrough T1D in advance should they anticipate any delays in submitting required documentation.)

If, after the probation period, the Grantee Institution fails to comply with these terms and conditions, further action may be taken, including but not limited to the termination of the Grant (see below).

7.2 Termination

7.2.1 Breakthrough T1D Termination for Convenience

Breakthrough T1D reserves the right to terminate a grant at any time, in whole or in part, for any reason.

7.2.2 Breakthrough T1D Termination For Cause

Breakthrough T1D may terminate a grant at any time for cause. Termination for cause under these Terms and Conditions shall include, but not be limited to: financial, ethical, administrative, or programmatic insufficiencies (for example, unreasonably prolonged and/or unexplained and unresolved delays in meeting project milestones), scientific misconduct, and/or the failure of the Grantee Institution to comply with these Terms and Conditions. Breakthrough T1D may 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 grant will be suspended until corrective actions are taken that are satisfactory as determined by Breakthrough T1D at their sole discretion. A termination of the grant for cause will not relieve the Grantee Institution of any breach of these Terms and Conditions or any other requirements of the grant.

7.2.3 Grantee Termination

Grants may also be terminated at any time by the Grantee Institution, in whole or in part, without cause. In such

cases, the Grantee Institution must provide Breakthrough T1D with written notice of termination. If a Grantee Institution elects to terminate a portion of their grant, Breakthrough T1D may determine that the remainder of the grant no longer meets Breakthrough T1D research mandates and may elect to terminate the remainder of the entire grant.

7.3 Modification of the Terms of the Award

During the grant period, should Breakthrough T1D scientific or grant personnel identify financial, administrative, or programmatic insufficiencies, Breakthrough T1D may place special conditions on the grant, including but not limited to those outlined in sections 7.1 and 7.2, above, if corrective actions are required. If special grant conditions must be imposed, Breakthrough T1D 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. Breakthrough T1D may also require the withdrawal of PI or other key personnel should Breakthrough T1D conclude that the PI and/or other key personnel are no longer competent to perform. Should this be the case, Breakthrough T1D may require that the Grantee Institution select a new PI and/or key personnel. All decisions to modify the terms of a grant (including withdrawal of PI or other personnel, or other special circumstances or conditions) will be exercised at Breakthrough T1D's discretion.

7.4 Recovery of Funds

Breakthrough T1D may administratively recover funds paid to the Grantee Institution in excess of the amount determined eligible under the terms of the grant (for example, and including but not limited to, error, misspent funds, or unallowable costs). Breakthrough T1D may require the Grantee Institution to pay back funds and will specify the terms and timeline for repayment. Additionally, Breakthrough T1D has the right to set off such amounts against any payment obligations of Breakthrough T1D to the Grantee Institution, including payments due from Breakthrough T1D under other grants. Breakthrough T1D may take any other actions permitted by law to recover such funds.

7.5 Surviving Terms

The following shall survive the expiration of the Grant and/or termination of this Agreement: Sections 1.2, 1.6-1.7, 5.6-5.12, 6.1, 6.4, and 7.4.

8. Appeals Procedures / Rebuttal

A PI under Administrative Probation or who has been given notice of other Breakthrough T1D 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 Breakthrough T1D. The Grantee Institution must send a rebuttal letter to Breakthrough T1D within 15 days of the probation/corrective action notification, at which time Breakthrough T1D, in its sole discretion, 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 they have read and agreed to these Terms and Conditions.

Authorized signing official full name: [populated by RO Contact upon accepting T&Cs in RMS]

Institutional Email Address: [automatically populates from RMS]

Execution date and time: [automatically populates from RMS]