



# Grant Handbook

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## 1. Introduction

Across the country and around the world, leading scientists are working to solve the many parts of the type 1 diabetes puzzle to deliver cures and life-improving breakthroughs. Breakthrough T1D helps fund their work, connects their research and propels advances forward with the aim of getting solutions to market as quickly as possible.

As the leading charitable funder of diabetes research worldwide, Breakthrough T1D offers a wide variety of grants and fellowships to qualified researchers.

We encourage all qualified researchers interested in solving the clinical and scientific problems associated with type 1 diabetes to apply for funding and become a part of our winning team.

## 2. Grant Mechanisms & Descriptions

Breakthrough T1D is a global funding agency with a substantial proportion of its grants awarded outside the United States. We encourage all qualified researchers interested in addressing the scientific and clinical challenges and gaps to cure type 1 diabetes and its complications to apply for funding. Decisions on funding are based on the quality, mission relevance, and priority of the proposed research. Breakthrough T1D encourages submission of innovative, high-risk/high-reward, field-changing research proposals to accelerate its mission.

Breakthrough T1D has multiple funding mechanisms, including Strategic Research Agreements, Innovative Grants, and Industry Grants to build a diverse research portfolio, to provide the research community with alternative approaches to address the foundation's mission, and to provide research training opportunities to attract new talent to the field.

View current [Grant Opportunity Deadlines](#).

## Breakthrough T1D Grant Mechanisms

### Ongoing Opportunities

**Grant Mechanism:** [Strategic Research Agreements](#) (Single Project, Multi-Project, and Clinical)

**Applicant Eligibility Requirements:** MD, DMD, DVM, DO, PhD, or equivalent and faculty position or equivalent

**Maximum Budget Per Year (USD):** As Approved

**Duration (Years):** As approved

**Letter of Intent (LOI) Required?:** Yes\*\*

**Grant Mechanism:** [Innovative Grants](#)

**Applicant Eligibility Requirements:** MD, DMD, DVM, DO, PhD, or equivalent and faculty position or equivalent

**Maximum Budget Per Year (USD):** \$200,000

**Duration (Years):** 1

**Letter of Intent (LOI) Required?:** No



## Training Opportunities

We regret that Breakthrough T1D is unable to consider applications in the area of diabetes related complications during the current fiscal year. Please direct any inquiries to the [Preward Support](#) inbox and a member of our team will respond.

**Grant Mechanism:** [Postdoctoral Fellowships](#)

**Applicant Eligibility Requirements:** MD, DMD, DVM, DO, PhD, or equivalent and must not be simultaneously serving an internship or residency

**Maximum Budget Per Year (USD):** Based on number of years' experience

**Duration (Years):** 3

**Letter of Intent (LOI) Required?:** No

**Grant Mechanism:** [Advanced Postdoctoral Fellowships](#)

**Applicant Eligibility Requirements:** MD, DMD, DVM, DO, PhD, or equivalent and must not be simultaneously serving an internship or residency

**Maximum Budget Per Year (USD):** \$95,000

**Duration (Years):** 3

**Letter of Intent (LOI) Required?:** No

**Grant Mechanism:** [Career Development Awards](#)

**Applicant Eligibility Requirements:** MD, DMD, DVM, DO, PhD, or equivalent and faculty position or equivalent

**Maximum Budget Per Year (USD):** \$200,000

**Duration (Years):** 5

**Letter of Intent (LOI) Required?:** No

**Grant Mechanism:** [Kellogg Family Early-Career Patient-Oriented Diabetes Research Awards](#)

**Applicant Eligibility Requirements:** MD, MD-PhD, or DO, hold an appointment or joint appointment in a subspecialty of clinical medicine, and conduct human clinical research

**Maximum Budget Per Year (USD):** \$200,000

**Duration (Years):** 5

**Letter of Intent (LOI) Required?:** No

## Other Opportunities

**Grant Mechanism:** [Conference Grants](#)

**Applicant Eligibility Requirements:** See Grant type description for eligibility criterion

**Maximum Budget Per Year (USD):** As approved

**Duration (Years):** n/a

**Letter of Intent (LOI) Required?:** Yes

**Grant Mechanism:** [Industry Discovery & Development Partnerships](#)

**Applicant Eligibility Requirements:** Biotechnology, pharmaceutical, device companies or other



for-profit entities; PI should be a MD, DMD, DVM, DO, PhD or equivalent, and hold a senior management position

**Maximum Budget Per Year (USD):** As approved

**Duration (Years):** Open

**Letter of Intent (LOI) Required?:** Yes\*\*

\*\*Successful completion of a **LOI** is required prior to submitting a full proposal for Strategic Research Agreements and Industry Discovery and Development Partnerships

## Grant Mechanisms – Detailed Information

### Strategic Research Agreement

#### Brief Description

Designed to provide research funding for investigators to address critical gaps and challenges and make breakthroughs in type 1 diabetes research.

#### Institutional Eligibility

Domestic & foreign non-profit organizations; public & private universities, colleges, hospitals, laboratories; units of state & local governments; eligible agencies of the federal government.

#### Applicant Eligibility

Required: MD, DMD, DVM, DO, PhD, or equivalent and faculty position or equivalent.

#### Human Subjects Research

For a project proposing human subject research, please review the [Human Subject Research Guidelines](#).

### Description

Breakthrough T1D’s Strategic Research Agreements provide research funding for investigators to address critical gaps and challenges and make breakthroughs in type 1 diabetes research. The Strategic Research Agreement is a partnership between Investigator(s) and Breakthrough T1D scientists to accelerate Breakthrough T1D’s mission through support of cutting-edge scientific investigation. Further, this mechanism embodies cooperative development of a research plan, regular reporting on milestones and interaction with Breakthrough T1D scientists prior to and during the award period. The budget and duration of funding are variable and continued funding is based on satisfactory effort and progress on milestones. Submission of an application requires permission from Breakthrough T1D and is initiated with an LOI submitted to [Project Concept Call in RMS360](#), an open [Breakthrough T1D Funding Opportunity](#), or by direct invitation from Breakthrough T1D Staff.

### Eligibility

Applicants must hold an MD, DMD, DVM, PhD, or equivalent and have a faculty position or equivalent at a college, university, medical school, company, or other research facility. Applications may be submitted by domestic and foreign non-profit organizations, public and private, such as



colleges, universities, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government. Ordinarily, for-profit organizations will not be considered, except under special circumstances. See the [Industry Discovery & Development Partnerships](#) section for a description of special programs for for-profit entities.

## Submitting an Application

### Step 1: Project Concept or Request for Application

An investigator interested in pursuing a research opportunity with Breakthrough T1D must submit an LOI through the project concept call or other open opportunity **in RMS360**. Full proposals are invited based on programmatic fit and robustness of the concept. In addition, projects that hold a prospect for transformative breakthroughs that prevent, treat or cure type 1 diabetes will be given top priority.

Applications are due at 5pm eastern on the deadline date, unless otherwise noted.

To view upcoming deadlines, click [here](#).

### Step 2: Full Application

If the applicant's LOI is approved by Breakthrough T1D, the applicant will be invited to submit a full research application. The applicant will be authorized to access and electronically submit the completed application via [RMS360](#).

1. The Breakthrough T1D scientific personnel works collaboratively with the investigator or investigator team to develop a full application in accordance with Breakthrough T1D strategic objectives.
2. All research applications are submitted and reviewed using RMS360.
3. The complete and submitted application is reviewed by internal and external scientific experts and written critiques are received by Breakthrough T1D staff.
4. The reviewers' written critiques will be shared with the applicant. Breakthrough T1D Staff may request a rebuttal from the applicant to address concerns raised by the reviewers.
5. The entire application and review materials are evaluated by Breakthrough T1D staff, reviewers, and go through Breakthrough T1D governance procedures.

**Note:** For a project proposing human subject research, please review the [Human Subject Research Guidelines](#).

## Terms of the Award

Available funding for the Strategic Research Agreement will be reviewed on a per-application basis. Projects will be milestone-driven and require teleconferences with Breakthrough T1D scientific staff to discuss project progress and research findings on a predetermined basis. In addition to quarterly or interim reports, an annual progress report will be due 1 month prior to the anniversary date of the award, except in the final year, in which the progress report is due 75 days following the close of the award. Indirect costs cannot exceed 10% of direct costs (direct costs do not include



equipment costs, fee-for-services, consultants, or subcontract costs).

## Clinical Strategic Research Agreement

### Description

Breakthrough T1D Clinical SRAs are intended to support research programs that qualify under the Breakthrough T1D clinical review process. This funding mechanism is intended to support clinical trials to test therapeutic approaches as well as non-interventional patient-oriented studies that are intended to lead to the development of clinical interventions and monitoring tools (such as biomarkers) for diabetes and its complications. Applications for Strategic Research Agreement – Clinical must be goal oriented and closely focused on the Breakthrough T1D mission.

### Clinical Application Guidelines

All applications involving human subject research must include supplemental information to address subject safety, study design and investigational product information. More details can be found in the [Human Subject Research Guidelines](#). All applications that receive a funding recommendation after scientific review will undergo clinical review where a subsequent review of the study protocol and supporting documents will be performed.

### Outcomes Beyond A1C Resources

The Steering Committee of the T1D Outcomes Program has defined the following outcomes: hypoglycemia, hyperglycemia, time-in-range, and diabetic ketoacidosis (DKA). Breakthrough T1D 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 see relevant resources - [fact sheet](#) and [video](#).

### Evaluation

Clinical SRAs will be evaluated for scientific merit, clinical standards of care for the proposed patient population and adherence to Good Clinical Practice. The scientific review criteria include:

- Relevance to the objectives of Breakthrough T1D
- Scientific, technical, or medical significance of the research proposal
- Innovative quality of the proposed study
- Soundness of the clinical study design
- Availability of sufficient pre-clinical data to justify the proposed clinical study
- Qualifications and research experience of the principal investigators and collaborators
- Consideration of the potential benefits and risks to patients who will be involved in the research, plans to limit risks, and other ethical considerations
- Availability of resources and facilities necessary for the study
- Appropriateness of the proposed budget in relation to the proposed research



## Clinical Trial Management (CTM)

The mission of this group at Breakthrough T1D is to facilitate execution of high-quality clinical trials. Please click the link for the current [Human Subject Research Guidelines](#) with a few additions as listed below.

- Pre-award: an application for funding can be submitted for bundled studies, pre-clinical and clinical piece, etc. but if deemed appropriate by the CTM, the below funding structures may apply requesting updated split budgets for each phase as applicable. No new application required.
  - multipart funding structure for clinical trial set up and execution phase, if applicable
  - if bundled trials within a single proposal, multipart funding structure
- Post-award: assigned Breakthrough T1D-CTM will provide active management of clinical trial grants via site calls to understand the study progress, as applicable.
- In some cases, it may be necessary for the CTM to perform a site visit either in advance of study initiation or during study conduct.

*Please speak with your proposal/study assigned [Breakthrough T1D staff](#) if you have any questions or need clarifications.*

## Postdoctoral Fellowship

Important: Applications in the area of LONG-TERM COMPLICATIONS will not be accepted.

### **Brief Description**

Designed to attract qualified, promising scientists entering their professional career in the T1D research field; intended for those in a relatively early state in their career

### **Institutional Eligibility**

Domestic & foreign non-profit organizations; public & private universities, colleges, hospitals, laboratories; units of state & local governments; eligible agencies of the federal government

### **Applicant Eligibility**

Required: MD, DMD, DVM, DO, PhD, or equivalent. Must not be simultaneously serving an internship or residency

### **Proposal**

Access and submit full applications (including research plans) via [RMS360](#).

### **Terms**

Total dollar amount varies based on years of relevant experience.

### **Human Subjects Research**

For a project proposing Human Subject Research, please review the [Scientific Guidelines](#).



## Description

Postdoctoral fellowships are designed to attract qualified, promising scientists entering their professional career in the T1D research field. The applicant is required to work with a sponsor who can provide a training environment conducive to beginning a career in type 1 diabetes-relevant research. At the time of activating the award, the applicant must have a doctoral degree (PhD, MD, DMD, DVM, DO), or the equivalent from an accredited institution and must not be simultaneously serving an internship or residency.

## Eligibility

### Applicant

This fellowship is intended for those at a relatively early stage of their career. Ordinarily, the most recent doctoral degree (PhD, MD, DMD, DVM, DO, or equivalent) will have been received no more than 5 years before the application is submitted.

Breakthrough T1D is sensitive to personal and COVID-related matters that impact career trajectories. Applicants who have taken leave from their career (e.g. parenting of a child, childbirth, long-term care of a parent/spouse/child/dependent, personal health issues), or experienced a delay in their training due to COVID shutdowns that put them outside of the eligibility time frame for the award mechanism should reach out to Breakthrough T1D staff ahead of their application submission. Breakthrough T1D aims to be flexible and adjust these time frames if necessary and appropriate.

### Sponsor

The applicant must be sponsored by an investigator who is affiliated full-time with an accredited institution and who agrees to supervise the applicant's training. The sponsor does not necessarily need to have a background in diabetes, but the research project must be type 1 diabetes related.

### Location

Fellowship research may be conducted at foreign and domestic, for-profit and nonprofit, and public and private organizations such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government.

## Proposal

Access and submit full applications (including research plans) via [RMS360](#).

## Research Plan

The research plan should be suitable for a three-year postdoctoral training period. The project should ask a specific and substantive question and be relevant to Breakthrough T1D's mission. Extensive discussion between the applicant and the proposed mentor is expected in order to identify an appropriate research project – one that is up-to-date, instructive, and suited to a three-year fellowship period.

The postdoctoral fellowship research plan may not exceed 7 pages, including figures and tables. Please note that the 7-page limit includes narrative items a through f, as described below. Proposals with research plans exceeding the page limit will not be considered.

The research plan must be organized as follows: a) Specific Aims, b) Background and Significance of this work to type 1 diabetes (provide a brief historical background of your proposed research, including major findings by you and/or others in relevant fields. Explain why you have chosen this problem), c) Preliminary Results (if available), d) Research Designs and Methods (describe, in detail, plans for solving problems, hypothesis, methodology, expected results, experimental subjects, controls, potential pitfalls and the rationale for the chosen approach), e) Other aspects (formal and informal) of the program that will contribute to the total training environment (examples include, but are not limited to, clinical experience with diabetic patients, interaction with senior professional with expertise in diabetes, participation in staff conferences, teaching, consultation, etc.), f) List any planned coursework, g) List pertinent literature references (no page limit).

**Note:** For a project proposing Human Subject Research, please review the [Scientific Guidelines](#).

At the end of the Research Plan section, the applicant must include a Future Career Plans statement and a Training Plan statement (see below).

## Future Career Plan Statement

The Future Career Plan Statement is limited to 2 pages. The applicant must include a statement of career goals and indicate the relevance of these goals to type 1 diabetes-related research. The future career plans statement should detail the applicant's plan for career development as an independent investigator. Topics to be discussed by the applicant may include: how much of the applicant's time will be protected for research; how the proposed research will contribute to the applicant's independent career; an expected timeline for obtaining an independent position, if the applicant is not already at that stage; how the Breakthrough T1D award will contribute to the applicant's future career plans; and any other planned formal or informal activities that will aid the applicant in establishing an independent research career. If the research proposed in the proposal is part of a larger research program or trial, the applicant should clearly define his/her role in the project and explain how their efforts on the project will lead to independence.

## Training Plan Statement (must be written by sponsor)

The sponsor must provide a biographical sketch, list of previous trainees, and a statement of the plan for training the applicant. The Training Plan is limited to 2 pages. This statement must outline a detailed training program for the applicant as well as confirm the availability of facilities to conduct the research project. The sponsor's statement should address plans for supervision, guidance, counseling, or other formal or informal training of the applicant. The sponsor must also include accurate and complete information regarding all other sources of grant support (current and pending), including title, abstract, annual and total amount of grant, inclusive funding period, and percent effort.

## Recommendation References

Three (3) recommendation references assessing the scientific abilities and potential of the applicant must be submitted. Please note that the recommendation references are confidential and will not be released to the applicant. The recommendation references must be submitted directly through RMS360 by the referee. Please note proposals cannot be successfully validated



until all references are submitted. Sponsors *cannot* be references but should complete the Training Plan Statement listed above.

## Evaluation

Fellowships will be awarded on the basis of the applicant's previous experience, academic record, the caliber of the proposed research, and the quality of the mentor, training program, and environment. The relevance of the proposal to the cause, cure, treatment, and/or prevention of diabetes and its complications will also be considered. Applicants are encouraged to submit projects aligned with [Breakthrough T1D Research Strategy](#). While not a requirement, a proposal that is aligned with Breakthrough T1D Priority areas will be given priority consideration in the review process.

The applicant's professional ability and promise for a research career in type 1 diabetes will hold the highest priority in selection and will be assessed on the basis of the letters of recommendation, career plans, prior clinical and research training, academic transcripts, and the mentor's endorsement. Location in a department that will provide a stimulating research environment is an additional factor that will be considered in evaluating applicants.

## Terms of Award & Stipend

Awards are for three years, assuming satisfactory progress. The fellowship term is 12 months for each fellowship year. Fellows must devote at least 75% of their effort to the project outlined in the fellowship proposal. Recipients of the Breakthrough T1D postdoctoral fellowship award cannot hold another postdoctoral fellowship at the same time.

Award amounts are based on years of relevant postdoctoral experience at the time of activation. There are no indirect costs allowed for fellowships and Breakthrough T1D will make no deductions for income tax, Social Security, etc. A research allowance of USD 5,500 is aimed at providing the fellow with funds to enrich their training experience and can be used for travel to scientific meetings (up to USD 2,000/year), journal subscriptions, books, training courses etc. They are not to be used for laboratory supplies or equipment. The purchase of a personal computer is allowed (up to USD 2,000) only during Year 1 of the award. Health insurance costs are permissible. The award is renewable for up to two additional years pending submission and approval of a renewal proposal and progress report. Please see [Breakthrough T1D's Administrative Resources](#) for awarded grants for more details about budget guidelines.

## Advanced Postdoctoral Fellowship

Important: Applications in the area of LONG-TERM COMPLICATIONS will not be accepted.

### Brief Description

Designed to attract qualified, promising scientists to receive full time research training and to assist these promising individuals in transitioning from a fellowship to an independent (faculty-level) position.



### **Institutional Eligibility**

Domestic & foreign non-profit organizations; public & private universities, colleges, hospitals, laboratories; units of state & local governments; eligible agencies of the federal government

### **Applicant Eligibility**

Required: MD, DMD, DVM, DO, PhD, or equivalent. Must not be simultaneously serving an internship or residency.

### **Proposal**

Access and submit full applications (including research plans) via [RMS360](#).

### **Terms**

95,000 USD maximum/year for up to 3 years

### **Human Subjects Research**

For a project proposing Human Subject Research, please review the [Scientific Guidelines](#).

## **Description**

The Advanced Postdoctoral Fellowship program is designed to attract qualified and promising health scientists, to provide an opportunity to receive full-time research training, and to assist these promising individuals in transitioning from a fellowship to an independent (faculty-level) position. Breakthrough T1D envisions the 3-year award term as a period in which fellows will receive critical research training that will position them to work at the leading edge of their chosen field. An additional, optional 1-year transition award will further assist fellows to proceed to independent faculty or research appointments and will serve as a bridge between the fellowship and independent competitive research funding. During the fellowship phase, the applicant is required to work with a sponsor who can provide a training environment conducive to beginning a career in diabetes-relevant research. At the time of activating the award, the applicant must have a doctoral degree (PhD, MD, DMD, DVM, DO, or equivalent) from an accredited institution and must not be simultaneously serving an internship or residency.

## **Eligibility**

### **Applicant**

This fellowship is intended for applicants who have completed some postdoctoral training, show extraordinary promise and are preparing for a transition to an independent research position. Generally, the most recent doctoral degree (PhD, MD, DMD, DVM, DO, or equivalent) will have been received no more than 6 years before the application is submitted.

Breakthrough T1D is sensitive to personal and COVID-related matters that impact career trajectories. Applicants who have taken leave from their career (e.g. parenting of a child, childbirth, long-term care of a parent/spouse/child/dependent, personal health issues), or experienced a delay in their training due to COVID shutdowns that put them outside of the eligibility time frame for the award mechanism should reach out to Breakthrough T1D staff ahead of their application submission. Breakthrough T1D aims to be flexible and adjust these time frames if necessary and appropriate.



### **Sponsor**

The applicant must be sponsored by an investigator who is affiliated full-time with an accredited institution and who agrees to supervise the applicant's training. The sponsor does not necessarily need to have a background in diabetes, but the research project must be diabetes related.

### **Location**

Fellowship research may be conducted at foreign and domestic, for-profit and nonprofit, and public and private organizations, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government.

## **Proposal**

Access and submit full applications (including research plans) via [RMS360](#).

## **Research Plan**

The advanced postdoctoral fellowship research plan may not exceed 7 pages, including figures and tables. Please note that the 7-page limit includes narrative items a through f, as described below. Proposals with research plans exceeding the page limit will not be considered.

The research plan must be organized as follows: a) Specific Aims, b) Background and Significance of this work to type 1 diabetes (provide a brief historical background of your proposed research, including major findings by you and/or others in the relevant field. Explain why you have chosen this problem), c) Preliminary Results (if available), d) Research Designs and Methods (describe, in detail, plans for solving problems, hypothesis, methodology, expected results, experimental subjects, controls, potential pitfalls and the rationale for the chosen approach), e) Other aspects (formal and informal) of the program that will continue to the total training environment (examples include, but are not limited to, clinical experience with diabetic patients, interaction with senior professional with expertise in diabetes, participation in staff conferences, teaching, consultation, etc.), f) List any planned coursework, g) List pertinent literature references (no page limit).

**Note:** For a project proposing Human Subject Research, please review the [Scientific Guidelines](#).

At the end of the Research Plan section, the applicant must include a Future Career Plans statement and a Training Plan statement (see below).

## **Future Career Plans Statement**

The Future Career Plans Statement is limited to 2 pages. The applicant must include a statement of career goals and indicate the relevance of these goals to type 1 diabetes-related research. The future career plans statement should detail the applicant's plan for career development as an independent investigator. Topics to be discussed by the applicant may include: how much of the applicant's time will be protected for research; how the proposed research will contribute to the applicant's independent career; an expected timeline for obtaining an independent position, if the applicant is not already at that stage; how the Breakthrough T1D award will contribute to the applicant's future career plans; and any other planned formal or informal activities that will aid the applicant in establishing an independent research career. If the research proposed in the proposal

is part of a larger research program or trial, the applicant should clearly define his/her role in the project and explain how their efforts on the project will lead to independence.

## Training Plan Statement (must be written by sponsor)

The sponsor must provide a biographical sketch, list of previous trainees, and a statement of the plan for training the applicant. The Training Plan is limited to 2 pages. This statement must outline a detailed training program for the applicant as well as confirm the availability of facilities to conduct the research project. The sponsor's statement should address plans for supervision, guidance, counseling, or other formal or informal training of the applicant. The sponsor must also include accurate and complete information regarding all other sources of grant support (current and pending), including title, abstract, annual and total amount of grant, inclusive funding period, and percent effort.

## Recommendation References

Three (3) recommendation references assessing the scientific abilities and potential of the applicant must be submitted. Please note that the recommendation references are confidential and will not be released to the applicant. The recommendation references must be submitted directly through RMS360 by the referee. Please note proposals cannot be successfully validated until all references are submitted. Sponsors *cannot* be references but should complete the Training Plan Statement listed above.

### Evaluation

Fellowships will be awarded on the basis of the applicant's previous experience, academic record, the caliber of the proposed research, the quality of the mentor, training program, and environment, and the applicant's potential to obtain an independent research position in the future. The relevance of the proposal to the cause, cure, treatment, and/or prevention of diabetes and its complications will also be considered. Applicants are encouraged to submit projects aligned with [Breakthrough T1D's Research Strategy](#). While not a requirement, a proposal that is aligned with Breakthrough T1D Priority areas will be given priority consideration in the review process.

The applicant's professional ability and promise for a research career in type 1 diabetes will hold the highest priority in selection and will be assessed on the basis of the letters of recommendation, career plans, prior clinical and research training, academic transcripts, and the mentor's endorsement. Location in a department that will provide a stimulating research environment is an additional factor that will be considered in evaluating applicants.

## Terms of Award & Stipend

Awards will be made for a duration of up to 3 years, assuming satisfactory progress. The fellowship term is 12 months for each fellowship year. Fellows must devote at least 75% of their effort to the project outlined in the fellowship proposal.

Budgets up to USD 95,000 per year for up to 3 years may be requested. The stipend request is based on years of relevant postdoctoral experience. Salary support for additional staff is not allowable.



There are no indirect costs allowed for fellowships and Breakthrough T1D will make no deductions for income tax, Social Security, etc. Funds in excess of the stipend, up to a total budget of USD 95,000 per year, can be used for travel to scientific meetings (up to USD 2,000/year), journal subscriptions, books, training courses, laboratory supplies, or equipment (in Year 1 only). The purchase of a personal computer is allowed (up to USD 2,000) only during Year 1 of the award. Health insurance costs are permissible. The award is renewable for up to two additional years pending submission and approval of a renewal proposal. Please see Breakthrough T1D's [Administrative Resources](#) for awarded grants for more details about budget guidelines.

## Transition Award

To assist the awardee's advancement to a faculty position, the advanced postdoctoral fellowship carries an optional transition year in which the awardee may request funding support in their first year as a faculty member of an academic institution. To apply for the transition year, awardees must provide a letter of institutional commitment and faculty appointment along with a satisfactory progress report and abbreviated research plan for the transitional year. The Transition Award can be requested in an amount up to USD 110,000 total costs for 1 year. Indirect costs (excluding equipment) cannot exceed 10 percent. The Transition Award can be requested at any time during the 3-year fellowship period after a faculty appointment has been obtained.

## Proposal

Transition award applicants should contact the relevant [Breakthrough T1D Research Administrator](#) to submit the required Transition Award materials.

## Career Development Award

Important: Applications in the area of LONG-TERM COMPLICATIONS will not be accepted. Applications in Psychosocial and Behavioral Health will be accepted.

### Brief Description

Designed to attract qualified and promising scientists early in their faculty careers and to give them the opportunity to establish themselves in areas that reflect the Breakthrough T1D research emphasis areas

### Institutional Eligibility

Domestic & foreign non-profit organizations; public & private universities, colleges, hospitals, laboratories; units of state & local governments; eligible agencies of the federal government

### Applicant Eligibility

Required: MD, DMD, DVM, DO, PsyD, PhD, or equivalent and faculty position or equivalent

### Proposal

Access and submit full applications (including research plans) via [RMS360](#).



## Terms

200,000 USD maximum/year for up to 5 years, including up to 10% for indirect costs and generally not renewable after 5 years

## Human Subjects Research

For a project proposing Human Subject Research, please review the [Scientific Guidelines](#).

## Description

Breakthrough T1D fosters the development and productivity of the best and the brightest established independent researchers who will bridge the gap between the bench and bedside. The primary purpose of the Career Development Award is to attract qualified and promising scientists early in their faculty careers and to give them the opportunity to establish themselves in areas that reflect the Breakthrough T1D research emphasis areas.

In the five-year term of the award, awardees will focus their research efforts on a subject directly related to Breakthrough T1D mission goals and [Breakthrough T1D Research Strategy](#), and position themselves to work at the leading edge of type 1 diabetes research. These awards are designed to assist exceptionally promising investigators. Although Breakthrough T1D is especially interested in fostering careers in clinical investigation, Career Development Awards may emphasize either basic or clinical topics.

## Eligibility

The Career Development Award is intended for individuals at an early stage of their independent academic career. Researchers who have received their first faculty-level appointment less than 3 years before the submission date are eligible to apply for this award. The applicant must hold an academic faculty-level position (including assistant professor or equivalent) at the time of submission of the proposal, at a university, health science center, or comparable institution with strong, well-established research and training programs for the chosen area of interest.

Breakthrough T1D is sensitive to personal and COVID-related matters that impact career trajectories. Applicants who have taken leave from their career (e.g. parenting of a child, childbirth, long-term care of a parent/spouse/child/dependent, personal health issues) or experienced a delay due to COVID shutdowns that puts them outside of the eligibility time frame for the award mechanism should reach out to Breakthrough T1D staff ahead of their application submission. Breakthrough T1D aims to be flexible and adjust these time frames if necessary and appropriate.

Career Development Award research may be conducted at foreign and domestic, for-profit and nonprofit, and public and private organizations – such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government.

## Proposal

Access and submit full applications (including research plans) via [RMS360](#).

## Research Plan

The Career Development Award research plan should describe a five-year project. The project should address a specific and substantive question that is relevant to the Breakthrough T1D mission. The research plan may not exceed 12 pages, including figures and tables, and should include narrative items a through d as described below. Proposals with research plans exceeding the page limit will not be considered.

The research plan must be organized as follows: a) Specific Aims; b) Background and Significance of this work to type 1 diabetes; c) Preliminary Studies (if applicable); d) Research Design and Methods; e) Literature Cited (no page limit).

**Note:** For a project proposing Human Subject Research, please review the [Scientific Guidelines](#).

## Future Career Plans Statement

At the end of the Research Plan section, the applicant must include a Future Career Plans statement, which is limited to 2 pages. The applicant must include a statement of career goals and indicate the relevance of these goals to type 1 diabetes-related research.

## Recommendation References

Three (3) recommendation references assessing the scientific abilities and potential of the applicant must be submitted. Please note that the recommendation references are confidential and will not be released to the applicant. The recommendation references must be submitted directly through RMS360 by the referee. Please note proposals cannot be successfully validated until all references are submitted.

## Institutional Assurance

The applicant's institution must, through the departmental supervisor, provide assurance of an academic commitment to the applicant and to the research project. This Department Head Statement must be included as a Supporting Document and uploaded as a proposal attachment.

## Evaluation

Awards will be made on the basis of the applicant's perceived ability and potential for a career in type 1 diabetes research, the caliber of the proposed research, and the quality and commitment of the institution. The applicant's professional ability and promise will hold the highest priority in selection and will be assessed on the basis of items such as letters of recommendation, publications, career plans, and prior clinical and research training.

## Terms of the Award

The award is up to USD 200,000 per year, including indirect costs. These funds may be used for a research allowance, which can include a technician, supplies, equipment and travel up to USD 2,000 per year. The awards are renewable pending satisfactory progress up to a maximum of four years. Salary for additional research personnel is permitted. Requests for equipment, in years other than the first year, must be strongly justified. Salary requests must be consistent with the established salary structure of the applicant's institution. Indirect costs (excluding equipment) may



not exceed 10% of subtotal direct costs. Please see Breakthrough T1D's [Administrative Resources](#) for awarded grants for more details about budget guidelines.

Awardees will be required to provide a progress report at the end of each funding year. Awards are renewable each year for a maximum of four years after submission and approval of a renewal proposal. Awardees must spend at least 75% of time and effort on type 1 diabetes-related research projects during the period of the award.

## Kellogg Family Early-Career Patient-Oriented Diabetes Research Award

Important: Applications in the area of LONG-TERM COMPLICATIONS will not be accepted. Applications in Psychosocial and Behavioral Health will be accepted.

### Brief Description

Designed to provide crucial support to investigators who plan to pursue a career in diabetes-related clinical investigation. Awards are made in the later stages of training and include the ability for recipients to transition to independent faculty or research appointments

### Institutional Eligibility

Domestic & foreign non-profit organizations; public & private universities, colleges, hospitals, laboratories; units of state & local governments; eligible agencies of the federal government

### Applicant Eligibility

In most cases, applicant will have an MD, MD-PhD, DO, or PsyD, hold an appointment or joint appointment in a subspecialty of clinical medicine, and conduct human clinical research

### Proposal

Access and submit full applications (including research plans) via [RMS360](#).

### Terms

200,000 USD maximum/year for up to 5 years, including up to 10% for indirect costs and generally not renewable after 5 years.

### Human Subjects Research

For a project proposing Human Subject Research, please review the [Scientific Guidelines](#).

### Upcoming Deadlines

See [Grant Opportunities and Deadlines](#)

## Eligibility

### Applicant

The Early Career Patient-Oriented Diabetes Research Award is intended for clinical researchers at a relatively early stage of their independent career. Clinical researchers who have received their first faculty-level appointment less than 5 years before the submission date are eligible to apply for this award. Applicants must have an MD, MD-PhD, DO, or PsyD, hold an appointment or joint



appointment in a subspecialty of clinical medicine in a clinical department, and conduct human clinical research. In exceptional circumstances, non-MD candidates will be considered if their work is likely to contribute significantly to a clinical outcome.

For the purposes of this award, clinical research is defined as research conducted with human subjects for which the investigator directly interacts with the subjects.

Breakthrough T1D is sensitive to personal and COVID-related matters that impact career trajectories. Applicants who have taken leave from their career (e.g. parenting of a child, childbirth, long-term care of a parent/spouse/child/dependent, personal health issues) or experienced a delay due to COVID shutdowns that puts them outside of the eligibility time frame for the award mechanism should reach out to Breakthrough T1D staff ahead of their application submission. Breakthrough T1D aims to be flexible and adjust these time frames if necessary and as appropriate.

### **Sponsor**

The applicant must be sponsored by an investigator who is affiliated full-time with an accredited institution, who pursues clinical research, and who agrees to supervise the applicant's training. The sponsor does not necessarily need to have a background in diabetes, but the research project must be type 1 diabetes-related and patient-oriented.

### **Location**

Research may be conducted at foreign and domestic, for-profit and nonprofit, and public and private organizations-such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government.

## **Proposal**

Access and submit full applications (including research plans) via [RMS360](#).

## **Research Plan**

The early career patient-oriented research plan may not exceed 12 pages, including figures and tables. Please note that the 12-page limit includes narrative items a through d as described below. The research plan must be organized as follows: a) Specific Aims; b) Background and Significance of this work to type 1 diabetes; c) Preliminary Studies (if applicable); d) Research Design and Methods; e) Literature Cited (no page limit). Proposals with research plans exceeding the page limit will not be considered.

**Note:** For a project proposing Human Subject Research, please review the [Scientific Guidelines](#).

At the end of the Research Plan section, the applicant must include a Future Career Plans statement and a Training Plan statement (see below).

## **Future Career Plans Statement**

The Future Career Plan Statement is limited to 2 pages. The applicant must include a statement of career goals and indicate the relevance of these goals to type 1 diabetes-related research. The future career plans statement should detail the applicant's plan for career development as an independent investigator. Topics to be discussed by the applicant may include: how much of the



applicant's time will be protected for research; how the proposed research will contribute to the applicant's independent career; an expected timeline for obtaining an independent position, if the applicant is not already at that stage; how the Breakthrough T1D award will contribute to the applicant's future career plans; and any other planned formal or informal activities that will aid the applicant in establishing an independent research career. If the research proposed in the proposal is part of a larger research program or trial, the applicant should clearly define his/her role in the project and explain how their efforts on the project will lead to independence.

## Training Plan Statement

The Training Plan Statement is limited to 4 pages. The *sponsor* must provide a biographical sketch, list of previous trainees, and a statement of the plan for training the applicant. This statement must outline a detailed training program for the applicant as well as confirm the availability of facilities to conduct the research project. The sponsor's statement should address plans for supervision, guidance, counseling, or other formal or informal training of the applicant.

The sponsor must also include accurate and complete information regarding all other sources of grant support (current and pending), including title, abstract, annual and total amount of grant, inclusive funding period, and percentage effort of the applicant.

## Recommendation References

Three (3) recommendation references assessing the scientific abilities and potential of the applicant must be submitted. Please note that the recommendation references are confidential and will not be released to the applicant. The recommendation references must be submitted directly through RMS360 by the referee. Please note proposals cannot be successfully validated until all references are submitted. Sponsors *cannot* be references but should complete the Training Plan Statement listed above.

## Institutional Assurance

Institutions should provide detailed evidence that their facilities are adequate for the proposed research, and that they have made a tangible commitment to fostering the career-development of clinical investigators conducting patient-oriented research. This Department Head Statement must be included as a Supporting Document and uploaded as a proposal attachment.

## Evaluation

Awards will be made to applicants who have demonstrated superior scholarship and show the promise for future achievement in clinical research, particularly in those areas that require the unique training of a clinical investigator. Applicants are encouraged to submit projects aligned with [Breakthrough T1D Research Strategy](#). While not a requirement, a proposal that is aligned with Breakthrough T1D Priority areas will be given priority consideration in the review process.

The initial step in the evaluation procedure for this award will be screening of the applicant by a panel of distinguished scientists. The panel, convened by Breakthrough T1D, will evaluate each candidate's qualifications and potential to conduct innovative patient-oriented research, as well as the quality and originality of the proposed research and its potential to advance clinical care. The panel will also consider the institutional environment, including laboratory and patient facilities



that will be available to the awardee. The final selection of the awardees will be made by Breakthrough T1D, based on the evaluations of the review panel.

## Terms of the Award

Awardees will be required to provide an annual progress report. Awards are renewable for a maximum of four years. Awardees must devote at least 75% of professional effort to the conduct of type 1 diabetes-related clinical research during the period of the award.

Awards are in the amount of up to USD 200,000 total costs per year, including indirect costs. Up to USD 100,000 of this may be requested for research allowance, which can include a technician, supplies, equipment, and travel up to USD 2,000 per year. Salary request must be consistent with the established salary structure of the applicant's institution, and equipment in years other than the first must be strongly justified. Indirect costs (excluding equipment) cannot exceed 10%.

Please see Breakthrough T1D's [Administrative Resources](#) for more details about budget guidelines.

## Innovative Grant

### Brief Description

The Innovative Grant program solicits proposals for highly innovative research with significant potential to accelerate the mission of Breakthrough T1D. Proposals should address key outstanding questions and have the potential to lead to a change in the current paradigm or conventional wisdom and/or lead to a groundbreaking discovery.

### Institutional Eligibility

Domestic & foreign non-profit organizations; public & private universities, colleges, hospitals, & laboratories; units of state and local governments; eligible agencies of the federal government

### Applicant Eligibility

Required: MD, DMD, DVM, PhD or equivalent and faculty position or equivalent

### Proposal

Access and submit full applications (including research plans) via [RMS360](#).

### Terms

Innovative: 200,000 USD maximum/year for one year, including up to 10% for indirect costs.

### Human Subjects Research

For a project proposing Human Subject Research, please review the [Scientific Guidelines](#).

## Description

Breakthrough T1D provides seed funding for highly innovative research with significant potential to accelerate the mission of Breakthrough T1D. Proposals should address key outstanding questions and have the potential to lead to a change in the current paradigm or conventional wisdom and/or lead to a groundbreaking discovery. Preliminary data is not required in the proposal, but the



underlying premise, goal, or hypothesis must be plausible and testable, and the proposal must be focused with a well-defined goal that is achievable within the timeframe of the award.

The Innovative Grant is not intended to support proposals aiming to incrementally advance existing hypotheses, ongoing areas of research or proposals with the sole goal of generating novel reagents or resources.

## Eligibility

Proposals may be submitted by domestic and foreign non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government. Innovative (but not pilot and research tool) proposals from for-profit organizations will also be considered. Applicants must hold an M.D., D.M.D., D.V.M., D.O., Ph.D., or equivalent and have a faculty position or equivalent at a college, university, medical school, or other research facility.

## Proposal

Access and submit full applications (including research plans) via [RMS360](#).

## Research Plan

The research plan must be submitted using the template available on RMS360 and may not exceed 3 pages, including figures and tables, but not including references. The research plan should include the following information: Statement of Innovation, Specific Aims, Background and Significance to T1D, Research Design and Methods, Potential Impact and Next Steps if Successful. **Note:** For a project proposing Human Subject Research, please review the [Scientific Guidelines](#).

## Evaluation

Proposals will be evaluated in accordance with the criteria described below. Evaluations will be competitive and performed by an appropriate review panel of Breakthrough T1D staff scientists. The review criteria include:

1. Innovation, potential impact, and relevance to Breakthrough T1D Research Strategy
2. Feasibility of experimental approach and ability to complete in one year
3. Clarity of proposed objectives and deliverables
4. Line of sight to immediate next steps if project is successful
5. Intent to leverage breakthroughs from other fields, as relevant (scientific or technical)
6. Qualifications of the principal investigators and collaborators
7. Availability of resources and facilities necessary for the project
8. Appropriateness of the proposed budget in relation to the proposed research

## Terms of the Award

Innovative grants provide one year of support for a maximum of USD 200,000, which includes 10% indirect costs. These grants are not renewable. A final progress report is due within 75 days following the close of the award.



Innovative proposals with significantly higher cost or requiring greater than one year of funding may still be considered for an Innovative Grant at the discretion of Breakthrough T1D. If you believe that your Innovative project requires a greater budget or funding period, please contact [Breakthrough T1D Program Scientist](#) in the relevant area to discuss possible options for submission.

Examples of innovative proposals that might be considered as exceptions include:

- Research that requires collaborative or multi-disciplinary approaches to address a single hypothesis
- Research that requires high-cost resources, e.g. costly reagents for genomics/ proteomics studies
- Studies that employ large-animal models or animal models that require lengthy development or distant endpoints

## Conference Grant

### Brief Description

Proposals for the support of scientific meetings, conferences, and workshops relevant to the Breakthrough T1D mission

### Institutional Eligibility

Domestic & foreign non-profit organizations; public & private universities, colleges, hospitals, laboratories; units of state & local governments; eligible agencies of the federal government

### Proposal

Access and submit full applications (including research plans) via Monday.com link below.

### Terms

Dollar amount awarded varies.

Breakthrough T1D does not cover indirect/overhead costs of any amount on conference grants. Please only include actual (direct) costs in your proposed budget.

## Description

Breakthrough T1D supports scientific meetings, conferences, and workshops relevant to its mission. Applications for conference support are accepted for consideration throughout the year. Note that the Breakthrough T1D Conference Grant does not provide individual support to an applicant for conference attendance.

## Eligibility

Each criterion will be considered in the context of how it relates to Breakthrough T1D research priorities:

1. How does the meeting/conference relate to Breakthrough T1D goals?
2. What is the format and agenda?
3. What is the need for the meeting/conference?
4. What is the timeliness of the meeting/conference?



5. What are the qualifications of the organizers and proposed participants?
6. What is the past performance of the meeting/conference (when applicable)?
7. How appropriate is the meeting site?
8. How appropriate is the budget?

## Proposal

Applications should be submitted through [this application form](#). Ensure all sections are accurately filled out and all required documents are attached. Please be mindful of the required [deadlines](#). Applications are reviewed on a rolling basis and are due ninety days prior to the meeting/workshop. Applicants will be notified within one month of the submission. *Incomplete or late grant applications will not be reviewed or considered.*

## Terms & Other Requirements

In general, complimentary registration for a designated member of Breakthrough T1D staff, or Breakthrough T1D guests, is required for Breakthrough T1D funding of a meeting. Breakthrough T1D funding must be acknowledged in all publicity and in the program for the meeting and any proceedings or publications resulting from the meeting. A summary of the meeting or its outcomes is due to Breakthrough T1D 4 weeks post meeting (can be topline). Copies of proceedings or publications resulting from the meeting must be provided to Breakthrough T1D. Breakthrough T1D reserves the right to post the meeting notice/agenda as well as other information related to the meeting on the Breakthrough T1D website. In addition, the application and summary may be used by Breakthrough T1D after the meeting for community updates and publicity on the Breakthrough T1D website. If the conference grant is approved, Breakthrough T1D will request an invoice. All invoices must be in USD and are due within 60 days of the request.

## Industry Discovery & Development Partnership

### Purpose

The Breakthrough T1D Industry Discovery & Development Partnership (IDDP) program is intended to provide support to for-profit entities for research programs that are closely aligned with Breakthrough T1D's priority areas. The program aims to accelerate the discovery, development, and commercialization of therapeutics and devices for the treatment, cure, and prevention of type 1 diabetes; and to foster long-term collaborative relationships among Breakthrough T1D, industry partners, and the T1D community. The IDDP program combines the capabilities of for-profit entities in moving forward treatments and therapies with commercial potential, with Breakthrough T1D's capabilities as a patient advocacy organization and supporter of T1D research worldwide.

### Eligibility and Strategic Alignment

The IDDP mechanism is intended for biotechnology, pharmaceutical, and other for-profit entities, either public or private. Projects may include company partnerships with academic investigators, contract research organizations (CROs), or other entities that enhance the research project. There are no geographical restrictions.



The industry partner must propose a project focused on the discovery and/or development of therapeutics and/or devices to cure, treat, and/or prevent T1D that is aligned with [Breakthrough T1D's Research Strategy](#). The proposal should include a description of the company's pipeline product(s) for T1D and a development path toward potential commercialization, with regulatory considerations included as appropriate.

## Matching Resources

Breakthrough T1D expects IDDP award recipients to demonstrate a commitment to carry the project to completion, and to plan for future commercialization of a T1D product that will have a meaningful impact for the T1D community. Applicants will be required to commit funding to the project in an amount equal to or greater than the amount requested from Breakthrough T1D, for the duration of the Breakthrough T1D funding (“matching resources” or “matched funds”).

In addition, applicants will be asked to provide audited financial statements (or audit report, if available) and fiscal projections as part of the due diligence process, and potentially throughout the duration of the proposed research project. The company is expected to continue commercially reasonable efforts to develop a T1D product(s) after the conclusion of Breakthrough T1D funding.

## Application and Review Process

IDDP applications and letters of intent (LOIs) are accepted by invitation from Breakthrough T1D on a rolling basis. LOIs may also be submitted in response to Breakthrough T1D Requests for Applications (RFA). Whether via an RFA or ad hoc, IDDP applicants should contact Breakthrough T1D staff before submitting an LOI.

### 1. Pre-LOI: Eligibility and Alignment Assessments

- Potential applicants must contact Breakthrough T1D Research staff prior to submitting an LOI. Discussions are facilitated with a non-confidential pitch deck and ideas for a potential research project.
- IDDP proposals must focus on a specific research project that is well-aligned with Breakthrough T1D research strategy.
- It is desirable for IDDP funding to bring a company to a defined inflection point in the path of product discovery, development, and/or regulatory approval.
- The applicant may choose to initiate a non-disclosure agreement (NDA).

### 2. Letter of Intent (LOI) and Term Sheet

#### (a) LOI and Project Plan

- LOIs for IDDPs are by invitation and must be submitted through RMS360. All documents submitted in RMS are covered by confidentiality.
- The LOI requirements include the following:
  - A concise description of the project plan, study design and methods, and end deliverables/goals.
  - Description of the company's leadership, key study personnel, and collaborators, including uploading biosketches of the Principal Investigator (PI) and any co-PIs.

- An overview of the company, including a summary of the company’s financials with supporting documents.
  - An outline of the budget request for Breakthrough T1D funds,
  - Description and amount of the company’s matching funds/resources for the proposed project.
  - The relevance for T1D and a clear outline of the company’s plans to develop the therapy and/or technology into a product for T1D.
- The LOI will be shared with Breakthrough T1D’s venture philanthropy team at the [T1D Fund](#).

(b) Non-binding Term Sheet

- If the LOI review is positive, the applicant will be invited to submit a full application and receive a non-binding term sheet.
- The term sheet outlines key terms for discussion before launching a definitive agreement.

### 3. Full Proposal and Agreement

(a) Full Proposal

- The full proposal will undergo external peer review by reviewers bound to keep materials confidential. This process may include the opportunity for the applicant to view anonymized critiques and provide a rebuttal. Breakthrough T1D may request the applicant consider modifications to the project plan in response to the peer review, and/or include reasons for not changing the plan via the rebuttal.
- The applicant should work with their Breakthrough T1D contact(s) throughout the submission process.

(b) Agreement

- Contingent upon agreement on the high-level terms in the term sheet, Breakthrough T1D will issue an agreement for review.
- A finalized definitive agreement is required for Breakthrough T1D to bring the IDDP funding opportunity for final approvals via standard Breakthrough T1D’s governance process.

Non-exclusivity: It is understood that Breakthrough T1D will continue to accept submissions and support activities across the field, including from non-profit and for-profit competing organizations.

## Agreement

Contract IDDP projects are administered and governed by an agreement negotiated between the parties (“Company” and Breakthrough T1D). All aspects of the relationship are described in the contract, including but not limited to the following:

1. Research scope, study design, key personnel, critical suppliers/supplies, etc.
2. Budget requested from Breakthrough T1D, alongside the budget for the Company’s matching funds/resources for the proposed project during the project period.
3. Governance by a Joint Research Advisory Committee (JRAC); financial and narrative reporting obligations

- Breakthrough T1D expects representation on a newly formed committee for the project
- 4. Milestones and Payments
  - Breakthrough T1D payments are made upon completion of pre-agreed progress milestones
- 5. Commercialization and Future Revenue Share (Royalties)
  - Breakthrough T1D will receive a modest return on investment (ROI), based on Company's successful commercialization of product(s) derived from the funded research program, and/or other inflection point(s) as mutually agreed in the contract.
  - Royalties will be capped at a proportion relative to the amount of the funded award. Financial terms depend on the stage of development of the funded research and the level of risk.
- 6. Company will own funded research discoveries, IP, and product rights.
- 7. Continuation of Commercially Reasonable Efforts (CRE) during and after Breakthrough T1D funding. In the event of interruption of CRE:
  - If Company decides to abandon further development and commercialization activities, Breakthrough T1D will expect access to the IP developed during the funded research program, with the right to sublicense to another entity committed to the necessary development toward commercialization in T1D.
- 8. Indemnification and Insurance.
- 9. Publications and Presentations.
- 10. Term and Termination.
- 11. Other standard terms and conditions, to be worked out with the definitive agreement.

## Contacts

The IDDP funding mechanism is managed by [Breakthrough T1D](#). For questions, please email [preawardsupport@breakthroughT1D.org](mailto:preawardsupport@breakthroughT1D.org).

Companies interested in the [T1D Fund](#), Breakthrough T1D's mission-driven venture philanthropy team, may email [t1dfund@breakthroughT1D.org](mailto:t1dfund@breakthroughT1D.org).

## 3. Application Guidelines

This page provides applicants with guidelines for application submission. Contact a member of [Breakthrough T1D Research Administrator](#) or reference the [RMS360 Pre and Post Award FAQs](#) for additional questions or for assistance with the application process.

### Application Guidelines Table of Contents

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## Introduction

Breakthrough T1D International is a leader in setting the agenda for diabetes research worldwide and is the largest charitable funder of and advocate for type 1 diabetes research. The mission of Breakthrough T1D is accelerating life-changing breakthroughs to cure, prevent and treat T1D and its complications.

Breakthrough T1D is a global funding agency with a substantial proportion of its grants awarded outside the United States. We encourage any and all qualified researchers interested in addressing the scientific and clinical challenges and gaps to cure type 1 diabetes and its complications to apply for funding. Decisions on funding are based on the quality, mission relevance, and priority of the proposed research. Breakthrough T1D encourages submission of innovative, high-risk/high-reward, field-changing research proposals to accelerate its mission.

Breakthrough T1D has multiple funding mechanisms to build a diverse research portfolio and to provide the research community with alternative approaches to address the foundation's mission and to provide research training opportunities to attract new talent to the field. A summary of the key features of each award type is presented below.

## General Information for Applicants

Potential applicants should note the following:

- Breakthrough T1D partners with various other national research organizations to leverage additional funds for diabetes research. The Breakthrough T1D research program is intended to complement, and not to replace, funding available from other organizations. Therefore, applicants to Breakthrough T1D research programs are urged to explore all potential funding sources, including other private organizations, government initiatives and consortia.
- Breakthrough T1D advocacy efforts have provided additional resources for type 1 diabetes research through the US National Institutes of Health (NIH). The NIH Type 1 Diabetes Special Statutory Funding Program provides research funding opportunities and access to special resources. Breakthrough T1D welcomes the participation of all investigators in accessing these opportunities and applicants should describe the use of these or other resources in their proposals.

- Breakthrough T1D is committed to the publication and dissemination of all information and materials developed using Breakthrough T1D resources. All recipients of Breakthrough T1D awards must agree to these principles and must take steps in order to facilitate availability of data and samples.

Applications for funding from Breakthrough T1D must have relevance to type 1 diabetes and [Breakthrough T1D Research Strategy](#).

## Application Review Process

Generally, applications undergo a pre-review process. For applications receiving a full review, critiques containing the reviewers' comments may be provided.

The Breakthrough T1D review process is either conducted internally by Breakthrough T1D Scientific Staff or externally by a Scientific Review Panel at the discretion of Breakthrough T1D Scientific Staff and Breakthrough T1D Senior Management. To assess the scientific merit and validity of any proposal, criteria for review include:

- Scientific validity and merit of proposed research
- Technical feasibility of proposed research
- Significance of the research:
  - Impact on accelerating discovery, development, or evaluation of type 1 diabetes therapeutics
  - Potential translation to human type 1 diabetes
  - Addressing a critical research gap
- Innovation:
  - Potential for change in a paradigm
  - Potential for a seminal discovery
  - Novel approaches to solving a problem
- Ability to complete the research in the funding period

For all applications, the Breakthrough T1D Scientific Team and Senior Management make final decisions regarding a proposal's scientific merit. Additional criteria for review include:

- Relevance of the proposed research to the overall Breakthrough T1D goals
- Relevance of the proposed research to specific research priorities
- Relevance of the proposed research in complementing the existing Breakthrough T1D project portfolio

Breakthrough T1D places particular importance on research that may be rapidly translated into clinical applications and research deemed to have the greatest impact.

Final approval for applications is determined by either Breakthrough T1D Senior Management or by a committee of the Breakthrough T1D International Board of Directors.

A summary of the general review process is as follows:

1. Letters of Intent (LOI) are submitted to Breakthrough T1D, if applicable
2. LOIs receive Internal and/or External review, if applicable

3. LOIs are triaged or approved for full Applications, if applicable
4. Full proposals are submitted to Breakthrough T1D
5. Full proposal receives Internal and/or External Scientific Review
6. Reviewers provide qualitative critiques and quantitative scores for the applications
7. Breakthrough T1D Scientific Staff make funding recommendation to Breakthrough T1D Senior Management
8. Breakthrough T1D Senior Management and/or a committee of the International Board of Directors make final funding decision

Applications may be eliminated from the review process for administrative reasons (Administrative Triage). An application may be administratively triaged if it does not fall into the [Breakthrough T1D Research Strategy](#), if it is incomplete, or if it otherwise does not meet Breakthrough T1D requirements.

Applicants will be notified in writing regarding the status of their application. Note that status of an application will not be given by phone.

## Application Content Requirements

All required information must be submitted online via the [RMS360](#) website (see [How to Apply](#) for specific instructions). Failure to submit all required application documents online, failure to submit a budget, biosketches, or any other component of the application, or failure to adhere to the guidelines below will result in administrative triage.

## Key Personnel

Applicants must provide contact information for key personnel in the designated section. Key Personnel is defined as participants in a grant or application who contribute substantively to the scientific development or execution of a project. Key personnel contribute a specified level of time whether or not earning a salary. Key personnel include the Principal Investigator as well as any consultants who meet the definition above. Percent effort should be provided for all Key Personnel in the budget section, whether they are claiming salaries or not.

## Application Budget

Funding requests must be submitted in US Dollars. Indirect costs must be specified on the budget page and are limited to 10% of direct costs (direct costs do not include equipment costs, fee-for-services, consultants, or subcontract costs). Breakthrough T1D follows U.S. National Institutes of Health (NIH) salary guidelines for [Principal Investigators](#) and [Postdoctoral Fellows](#). Breakthrough T1D guidelines are adjusted when new NIH guidelines go into effect.

## Other Sources of Support

Applicants must include accurate and complete information regarding all other sources of grant support from the main PI (current and pending), including title, abstract, annual and total amount of the grant, inclusive funding period, and percent effort of the applicant. For Postdoctoral and Advanced Postdoctoral Fellowships, Other Support information should be provided for the Sponsor/Mentor only.



## Biosketch

A Biosketch should be uploaded in the Proposal Attachments section for the PI, Co-PI, Other faculty-level investigators including collaborators and consultants, and Subcontract PI/investigators.

\*The Breakthrough T1D biosketch or NIH biosketch format is acceptable.

## Other Application Content Requirements

The application must include a complete mailing, phone, and email address and must include 2 abstracts, one written for a scientific audience and one for a lay audience. The lay audience abstract must be broken out into 6 categories as outlined in the application:

1. General Audience Summary
2. Technical Abstract
3. Objective
4. Background/Rationale
5. Anticipated Outcome
6. Relevance to type 1 diabetes

Each abstract category has a 600-word limit.

**Please note that if the guidelines outlined above are not followed, the application will be administratively triaged.**

## Human Subjects Research Application Requirements

All applications proposing research with human subjects or human fetal tissue, regardless of grant mechanism, must follow the [Scientific Guidelines](#). Human Subject applications without appropriate supplemental information will be administratively triaged.

If you are unsure if your proposed study involves human subjects, please see [Breakthrough T1D Applicant Guidelines for Clinical Classification](#).

For more information on the **Clinical Trial Management group**, please click [here](#).

## Resubmissions

Breakthrough T1D accepts applications resubmitted after rejection by the Breakthrough T1D review committee(s) discussed above. All resubmitted applications must include:

A copy of the summary statement for the original application if provided for rejected submission.  
An introduction (limited to two pages) addressing each of the reviewer's concerns if provided for the rejected submission.

These documents must be included in the Resubmission section of the Research Plan.

## Starting a Breakthrough T1D Electronic Application

Applicants applying for any Breakthrough T1D award types must begin their application by registering as a [RMS360](#) user.



RMS360 is Breakthrough T1D's web-based grant management service provider. Visit the site to register and apply. If you are a Breakthrough T1D Peer Reviewer with a preexisting Reviewer account, please use the same login information to apply for a Breakthrough T1D grant.

Applicants from for-profit entities should refer to the [Industry Discovery & Development Partnerships](#) page for information on Breakthrough T1D funding programs for industry and how to apply.

## Completing an Electronic Application

Begin your application submission process by creating a [RMS360](#) account or by logging in with your current account if you had previously been registered as either a reviewer or an applicant (see above).

1. Log onto [RMS360](#).
2. Complete your profile if you have not done so in order to access the applications
3. Select the appropriate application from the list of Breakthrough T1D funding opportunities.
4. Click the Apply Now link to gain access to the application template.
5. Complete each of the proposal sections listed in the online application (i.e. Contacts, Application Type, Project Description/Abstracts, etc.)
6. Remember to select "Save Draft" regularly throughout the online application to ensure that your work is saved.
7. Click on the Additional Attachments link and download the appropriate supplemental template.
8. To complete the online submission, click the "Validate and Submit Proposal to RO" button. Work directly with your RO to ensure the Validation and Submission process, as outlined below, is completed prior to the submission deadline.

## RMS360 Templates

### Using Templates

The Proposal Attachments section of the application contains downloadable files. The files include templates and instruction documents. Click the download link to save a template to your computer. You will complete each template offline. Use MS Word or MS Excel (depending on the template) to complete the template documents, then convert each file to PDF and upload the completed attachment files to your online application (see below for more information).

**Please note that PDF proposal attachments should not be locked, password encrypted or protected. Please confirm this before uploading to your application.**

Some of the files you will download are required attachments. All required attachments will be indicated as such. Once you upload a completed required template, the template name will display in the "Current List of Uploaded Attachments" menu. The "Validate" link, located in the gray navigation menu and available from every online page of the online application, can also serve as a tool for you to check to ensure that at least one of each of the required attachments is included in your application.



### Uploading Completed Templates

Once you have converted your application template to PDF, you must then upload the file(s) to your online application. Follow the following steps:

1. Open your application in RMS360 and navigate to the Additional Attachments section page
2. Click on the blue button that says upload and then browse for your attachment
3. Select appropriate attachment and click start upload and then close the text box

The file is now attached to the application and should now be listed in the Additional Attachments section.

If, for any reason, you wish to modify the file, make the revisions in the original document (offline), convert the updated file to PDF and attached the revised file to the application. Delete previously submitted versions of the file.

## Validation and Final Submission

To submit the final application, you must first validate your application to ensure that all required files are attached and that all required entries on all pages of the application have been completed as required. Click the “Validate and Submit Proposal to RO” link to submit your application to your Research Office contact (RO). Following this action, the RO will receive an email notifying them of your submission. In order for your submission to be considered complete, the RO must log into RMS360, approve the project budget, and select the “Submit to Breakthrough T1D” button. Please work directly with your RO to ensure this process is completed prior to the submission deadline.

**Special Note:** The final submission of your proposal to Breakthrough T1D (via [RMS360](#)) automatically indicates to Breakthrough T1D that the PI and his/her administrative and financial officials, sponsors, and/or department heads certify that the statements within their Breakthrough T1D proposal are true, complete, and accurate to the best of their knowledge, and accept the obligation to comply with Breakthrough T1D’s **non-negotiable [Terms and Conditions](#)** if the grant is awarded as a result of the application. It further certifies that they are aware that any false, fictitious, or fraudulent statements or claims may subject the PI and the PI’s officials to criminal, civil, or administrative penalties.

## Application Formatting Requirements

### File Size

Limit the file size of each uploaded attachment to 3-4 MB.

### Images and Text Formatting

Do not use text boxes.

1. When incorporating figures into the text of your application document(s), follow these steps:
  - a.) Save your figures as individual .jpg or .gif files. Make sure your figures are not inserted into a text box. Do not use other graphic file types (e.g., .tif).
  - b.) In your MS Word Research Plan document, select “Insert>Picture>From File” in the “Insert” menu. Select the .jpg file you created and click on the “Insert” button.

2. Type size limitations must be observed throughout the application. Use 10-point size font only. Figure legends, footnotes, and aspects of charts and tables may be smaller in font size but must still be clear and legible.
3. Margins, in all directions, must be at least 1/2 inch.
4. Be consistent with font styles and indentation.

#### **Other Requirements**

Use English only and avoid jargon and unusual abbreviations.

1. Do not include your social security number or passport number in your Breakthrough T1D application.

**Please note that if the guidelines outlined above are not followed, the application will be administratively triaged and will not receive a review.**

## 4. Application Checklists

The following checklists have been prepared to assist you in completing your Breakthrough T1D Application. Please utilize the appropriate checklist to ensure your application is complete prior to submission. Note that incomplete applications may be administratively triaged prior to scientific peer review – visit the [Application Guidelines](#) for more information.

- [Strategic Research Agreements](#)
- [Innovative Awards](#)
- [Postdoctoral Fellowships](#)
- [Advanced Postdoctoral Fellowships](#)
- [Career Development Awards](#)
- [Early Career Patient-Oriented Diabetes Research Award](#)
- [Industry Discovery & Development Partnerships \(IDDP\) Program](#)

Visit [RMS360](#) to submit your application.

### Strategic Research Agreements Application Checklist

#### **Applicant Information**

- Has a PhD/MD/DMD/DVM/DO or the equivalent from an accredited institution at award activation
- The applicant's institution is a nonprofit or academic entity
- Holds a faculty level position or equivalent at a college, university, medical school, or other research facility

#### **Contacts**

- Principal Investigator Biosketch is up to date within profile

*Contact information is provided for:*

- Principal Investigator

- Co-Principal Investigator (*if applicable*)
- Research Delegate (*if applicable*)
- Key Personnel (*if applicable*)
- Research Officer/Finance Officer

#### **Application Type**

- Research priority area in application
- Alternate research priority area in application
- Is the application a resubmission? Select **YES** or **NO**
  - If yes, please include Summary Statement from the previous application
  - Rebuttal Letter (*included in the research plan and does not exceed 2 pages*)
- Indicate yes/no if you agree to allow Breakthrough T1D to share this application with The Leona M. and Harry B. Helmsley Charitable Trust for potential co-funding, under the Breakthrough T1D confidentiality policy
- Clinical classification (if applicable)

#### **Other Support**

- Applicant included accurate and complete information regarding all other sources of grant support from the main Principal Investigator (current and pending), including title, abstract, annual and total amount of the grant, inclusive funding period, and percent effort of the applicant.
- Indicate if any leverage (Other funds or donated resources received from funders or partners outside of the applicant institution that directly support the project described)

#### **Project Descriptions/Abstracts**

- All mandatory text boxes are filled-in

#### **Organization Assurances**

- Human Subjects
  - Use of human subject research indicated in the application? (*if applicable*)
  - Uploaded Human Subject Research Plan (*if applicable*)
- Vertebrate Animals
  - Use of animals indicated in the application? (*if applicable*)

#### **Proposal Research Plan**

- 12 pages maximum unless noted otherwise on RFA call document

#### **Milestones and Timelines**

- Please enter a Milestone Description and Projected Completion Date for each milestone added

#### **Additional Attachments**

- Biosketch(es) to be uploaded:
  - Principal Investigator
  - Key Personnel (if applicable)

- Other Faculty Level Investigators: Collaborators, Consultants, Subcontract Investigators, etc. *(if applicable)*
- *Upload only if applicable:*
  - Human Subject Research Plan *(if applicable)*
  - Protocol Synopsis
  - Resources
  - Supporting Documents
  - Diversity & Inclusion Resource Sheet

### **Budget**

- Followed the Breakthrough T1D budget guidelines (see below)
- Has sufficient justification been provided for applicable budget categories
- All of the Principal Investigators and key personnel are listed as salary line items and percent effort is indicated
- Expenses are consistent with Breakthrough T1D cost principles and sufficient justification is provided
- No unallowable costs included in the budget (see below)

### **Breakthrough T1D Budget Guidelines**

- **Salaries and Wages** include wages earned by an employee and may include benefits, such as insurance and retirement plans.
  - All personnel listed in the grant (including all key personnel) must be included in the budget and in the personnel justification
  - If the Principal Investigator is not taking a salary from the grant, then their base salary is \$0.00 but a percent effort and justification must still be provided.
  - The percent effort listed in the justification should match the percent effort in the line item budget.
  - Confirm that all salaries requested are for personnel at the grantee institution. (see **subcontracts** and **consultants** below).
- **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.
  - Supply costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.
- **Travel Costs** may include any domestic and/or international trips by an employee related to the project and is limited to \$2,000 USD per year.
  - Travel costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.
- **Equipment Costs** can only be requested in year one.
  - Equipment costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.
- **Other Costs** might include items that are not consumable but are needed on a regular basis, such as animal purchases and maintenance changes. Consultants are listed here.
  - **Consultants** are individuals hired to give professional advice or services for a fee. These individuals are typically presented at zero percent effort or as needed

(individuals with measurable effort cannot be listed as consultants). The services to be performed by the consultant(s) must be included in the justification along with the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs for each.

- Other costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.
- **Indirect Costs** cannot exceed 10% of direct costs.

**Subcontracts** are for individuals or entities that contribute to the execution or design of the project, are key personnel on the grant, and/or have measurable percent effort but are not an employee of the grantee institution.

- Subcontracts have the same rules as the main budget (i.e. travel cannot exceed \$2,000, equipment can only be requested in year one, etc.).
- Supplies, travel, equipment, and other costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.

***For all grant mechanisms, the non-exclusive list of non-allowable costs includes:***

- Lobbying
  - Breakthrough T1D 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
- Office Telecommunications
- Advertising Costs
- Patent Applications
- Indirect Cost for Fee for Services, Consultants, and Contractors

For additional information please consult the [Breakthrough T1D website](#), peruse the rest of this document, or review [Breakthrough T1D's pre and post award FAQs](#).

## Innovative Awards Application Checklist

### Applicant Information

- Has a PhD/MD/DMD/DVM/DO or the equivalent from an accredited institution at award activation
- The applicant's institution is a nonprofit or academic entity
- Holds a faculty level position or equivalent at a college, university, medical school, or other research facility

### **Contacts**

- Principal Investigator Biosketch is up to date within profile

Contact information is provided for:

- Principal Investigator
- Co-Principal Investigator (*if applicable*)
- Research Delegate (*if applicable*)
- Key Personnel (*if applicable*)
- Research Officer/Finance Officer

### **Application Type**

- Research priority area in application
- Alternate research priority area in application
- Is the application a resubmission? Select **YES** or **NO**
  - If yes, please include Summary Statement from the previous application
  - Rebuttal Letter (*included in the research plan and does not exceed 2 pages*)
- Indicate yes/no if you agree to allow Breakthrough T1D to share this application with The Leona M. and Harry B. Helmsley Charitable Trust for potential co-funding, under the Breakthrough T1D confidentiality policy
- Clinical classification (*if applicable*)

### **Other Support**

- Applicant included accurate and complete information regarding all other sources of grant support from the main Principal Investigator (current and pending), including title, abstract, annual and total amount of the grant, inclusive funding period, and percent effort of the applicant.
- Indicate if any leverage

### **Project Descriptions/Abstracts**

- All mandatory text boxes are filled-in

### **Organization Assurances**

- Human Subjects
  - Use of human subject research indicated in the application? (*if applicable*)
  - Uploaded Human Subject Research Plan (*if applicable*)
- Vertebrate Animals
  - Use of animals indicated in the application? (*if applicable*)

### **Proposal Research Plan**

- Research Plan (sections A-F do not exceed 3 pages)

### **Additional Attachments**

- Biosketch(es) to be uploaded:
  - Principal Investigator

- Key Personnel (*if applicable*)
- Other Faculty Level Investigators: Collaborators, Consultants, Subcontract Investigators, etc. (*if applicable*)
- **Upload only if applicable:**
  - Human Subject Research Plan (*if applicable*)
  - Protocol Synopsis
  - Resources
  - Supporting Documents
  - Diversity & Inclusion Resource Sheet

### **Budget**

- The maximum total cost requested does not exceed \$200,000 (USD) per year, including 10% indirect costs.
- All of the Principal Investigators and key personnel are listed as salary line items and percent effort is indicated (even if they are not taking salary from the grant they must be listed as a line item and justified in the salary justification section).
- Sufficient justification has been provided for applicable budget categories.
- Expenses are consistent with Breakthrough T1D cost principles.
- Followed the Breakthrough T1D budget guidelines (see below).
- No unallowable costs included in the budget (see below).

### **Breakthrough T1D Budget Guidelines**

- **Salaries and Wages** include wages earned by an employee and may include benefits, such as insurance and retirement plans.
  - All personnel listed in the grant (including all key personnel) must be included in the budget and in the personnel justification
  - If the Principal Investigator is not taking a salary from the grant, then their base salary is \$0.00 but a percent effort and justification must still be provided.
  - The percent effort listed in the justification should match the percent effort in the line item budget.
  - Confirm that all salaries requested are for personnel at the grantee institution. (see **subcontracts** and **consultants** below).
- 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.
  - Supply costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.
- **Travel Costs** may include any domestic and/or international trips by an employee related to the project and is limited to \$2,000 USD per year.
  - Travel costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.
- **Equipment Costs** can only be requested in year one.

- Equipment costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.
- **Other Costs** might include items that are not consumable but are needed on a regular basis, such as animal purchases and maintenance changes. Consultants are listed here.
  - **Consultants** are individuals hired to give professional advice or services for a fee. These individuals are typically presented at zero percent effort or as needed (individuals with measurable effort cannot be listed as consultants). The services to be performed by the consultant(s) must be included in the justification along with the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs for each.
  - Other costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.
- **Indirect Costs** cannot exceed 10% of direct costs.

**Subcontracts** are for individuals or entities that contribute to the execution or design of the project, are key personnel on the grant, and/or have measurable percent effort but are not an employee of the grantee institution.

- Subcontracts have the same rules as the main budget (i.e. travel cannot exceed \$2,000, equipment can only be requested in year one, etc.).
- Supplies, travel, equipment, and other costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.

**For all grant mechanisms, the non-exclusive list of non-allowable costs includes:**

- Lobbying
  - Breakthrough T1D 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
- Office Telecommunications
- Advertising Costs
- Patent Applications
- Indirect Cost for Fee for Services, Consultants, and Contractors

For additional information please consult the [Breakthrough T1D website](#), peruse the rest of this document, or review [Breakthrough T1D's pre and post award FAQs](#).

## Postdoctoral Fellowships Application Checklist

### Applicant Information

- Has a PhD/MD/DMD/DVM/DO or the equivalent from an accredited institution at award activation
- Has received their first degree no more than 5 years before the fellowship and would not be simultaneously serving an internship or residency
- Does not hold a faculty appointment
- The applicant's institution is an academic or nonprofit entity
- The Principal Investigator is devoting at least 75% of their time and effort on the project during the period of the award

### **Contacts**

- Principal Investigator Biosketch is up to date within profile

*Contact information is provided for:*

- Principal Investigator
- Co-Principal Investigator (*if applicable*)
- Research Delegate (*if applicable*)
- Key Personnel (*if applicable*)
- Research Officer/Finance Officer

### **Application Type**

- Research priority area in application
- Alternate research priority area in application
- Is the application a resubmission? Select **YES** or **NO**
  - If yes, please include Summary Statement from the previous application
  - Rebuttal Letter (*included in the research plan and does not exceed 2 pages*)
- Indicate yes/no if you agree to allow Breakthrough T1D to share this application with The Leona M. and Harry B. Helmsley Charitable Trust for potential co-funding, under the Breakthrough T1D confidentiality policy
- Clinical classification (*if applicable*)

### **Other Support**

- Completed only for the Sponsor
- Indicate if any leverage

### **Project Descriptions/Abstracts**

- All mandatory fields have been completed

### **Organization Assurances**

- Human Subjects
  - Use of human subject research indicated in the application? (*if applicable*)
  - Uploaded Human Subject Research Plan (*if applicable*)
- Vertebrate Animals
  - Use of animals indicated in the application? (*if applicable*)

### **Proposal Research Plan**

- Introduction to Revised Application (2 pages maximum)
- Research Plan (7 pages maximum)
- Future Plans (2 pages maximum)
- Training Plans (written by the Sponsor, includes list of previous trainees, 2 pages maximum)

### **Additional Attachments**

- Biosketch(es) to be uploaded:
  - Principal Investigator
  - Mentor/Sponsor
  - Key Personnel (if applicable)
  - Other Faculty Level Investigators: Collaborators, Consultants, Subcontract Investigators, etc. (if applicable)
  - Collaboration Letters Uploaded under Supporting documents (if applicable)
- *Upload only if applicable:*
  - Human Subject Research Plan (if applicable)
  - Protocol Synopsis
  - Resources
  - Supporting Documents
  - Diversity & Inclusion Resource Sheet

### **Budget**

- Followed the Breakthrough T1D budget guidelines outlined in the budget document below.
- The correct years of experience at the time of activation of the award is selected.
- The applicant is devoting at least 75% of their effort to the project outlined in the fellowship application.
- Expenses are consistent with Breakthrough T1D cost principles and sufficient justification for the research allowance is provided.
- No unallowable costs included in the budget.

### **Breakthrough T1D Budget Guidelines**

- **Stipend**
  - The PI role must be justified
  - Applicants must devote 75% of their effort to the award. Salary support for additional staff is not allowed.
- **Research Allowance**
  - Postdoctoral Fellows are given a research allowance of \$5,500 per year. The research allowance should be justified in the Salary/Wage/Stipend/Research Allowance Justification.
    - Computer purchases of up to \$2,000 are allowable in year one only.
    - Travel may include any domestic and/or international trips by the Postdoctoral Fellow related to the project and is limited to \$2,000 USD per year.
    - Health Insurance costs are allowed.

***The non-exclusive list of non-allowable costs includes:***

- Lobbying
  - Breakthrough T1D grant funds may not be used for lobbying purposes of any kind.
- Tuition and Registration Fees
- General Office Supplies/Equipment
- Administrative Assistance Costs
- Financial Analyst, Accountant Cost
- Rent
- Office Telecommunications
- Advertising Costs
- Patent Applications
- Indirect Cost for Fee for Services, Consultants, and Contractors

For additional information please consult the [Breakthrough T1D website](#), peruse the rest of this document, or review [Breakthrough T1D's pre and post award FAQs](#).

## Advanced Postdoctoral Fellowships Application Checklist

### Applicant Information

- Has a PhD/MD/DMD/DVM/DO or the equivalent from an accredited institution at award activation
- Has received their first degree **no more than 6** years before the fellowship and would be not simultaneously serving an internship or residency
- The applicant's institution is a nonprofit or academic entity
- Does not hold a faculty appointment

### Contacts

- Principal Investigator Biosketch is up to date within profile

*Contact information is provided for:*

- Principal Investigator
- Research Delegate (if applicable)
- Research Officer/Finance Officer
- Recommendation References (blind) 3 required (sponsor not allowed as a reference)
- Mentor/Sponsor
  - The Sponsor is affiliated full-time with an accredited institution and agrees to supervise the applicant's training

### Application Type

- Research priority area in application
- Alternate research priority area in application
- Is the application a resubmission? Select **YES** or **NO**
  - If yes, please include Summary Statement from the previous application

- Rebuttal Letter (*included in the research plan and does not exceed 2 pages*)
- Indicate yes/no if you agree to allow Breakthrough T1D to share this application with The Leona M. and Harry B. Helmsley Charitable Trust for potential co-funding, under the Breakthrough T1D confidentiality policy
- Clinical classification (if applicable)

#### **Other Support**

- Completed only for the Sponsor
- Indicate if any leverage

#### **Project Descriptions/Abstracts**

- All mandatory text boxes are filled-in

#### **Organization Assurances**

- Human Subjects
  - Use of human subject research indicated in the application? (*if applicable*)
  - Uploaded Human Subject Research Plan (*if applicable*)
- Vertebrate Animals
  - Use of animals indicated in the application? (*if applicable*)

#### **Proposal Research Plan**

- Introduction to Revised Application (2 pages maximum)
- Research Plan (7 pages maximum)
- Future Plans (2 pages maximum)
- Training Plans (written by the Sponsor, includes list of previous trainees, 2 pages maximum)
- Budget
- Followed the Breakthrough T1D budget guidelines outlined in the document below
- The correct years of experience at the time of activation of the award is selected. Applicants cannot have 0 years experience
- The maximum total cost requested does not exceed \$95,000 (USD) per year
- The applicant is devoting at least 75% of their effort to the project outlined in the fellowship application
- Expenses are consistent with Breakthrough T1D cost principles and sufficient justification is provided
- No unallowable costs included in the budget

#### **Additional Attachments**

- Biosketch(es) to be uploaded:
  - Principal Investigator
  - Mentor/Sponsor
  - Key Personnel (if applicable)
  - Other Faculty Level Investigators: Collaborators, Consultants, Subcontract Investigators, etc. (if applicable)
- *Upload only if applicable:*
  - Human Subject Research Plan (if applicable)

- Protocol Synopsis
- Resources
- Supporting Documents
- Diversity & Inclusion Resource Sheet

### **Breakthrough T1D Budget Guidelines**

- **Stipend** must correspond with the years of experience at the time of the start of the grant
  - The PI role must be justified
  - Applicants cannot have zero years of experience.
  - Applicants must devote 75% of their effort to the award. Salary support for additional staff is not allowed.
- **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.
  - Supply costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.
- **Travel Costs** may include any domestic and/or international trips by an employee related to the project and is limited to \$2,000 USD per year.
  - Travel costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.
- For **Other Costs**, computer purchases of up to \$2,000 are allowable in year one only. Advanced Postdoctoral Fellows may request health insurance in this section.
  - Other costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.
- **Equipment** can only be requested in year one.
  - Equipment costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.
- **Indirect Costs** cannot exceed 10% of direct costs.

### ***The non-exclusive list of non-allowable costs includes:***

- Lobbying
  - Breakthrough T1D 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
- Office Telecommunications
- Advertising Costs
- Patent Applications
- Indirect Cost for Fee for Services, Consultants, and Contractors

For additional information please consult the [Breakthrough T1D website](#), peruse the rest of this document, or review [Breakthrough T1D's pre and post award FAQs](#).

## Career Development Awards Application Checklist

### Applicant Information

- Has a PhD/MD/DMD/DVM/DO or the equivalent from an accredited institution at award activation
- Holds an academic faculty level position (including assistant professor or equivalent) at the time of the proposal at a university, health science center, or comparable institution with strong, well-established research and training programs for the chosen area of interest
- Has received their first faculty level appointment less than 3 years before submission date
- The applicant's institution is a nonprofit or academic entity
- The Principal Investigator is devoting at least 75% of their time and effort on type 1 diabetes related research projects during the period of the award

### Contacts

- Principal Investigator Biosketch is up to date within profile

Contact information is provided for:

- Principal Investigator
- Co-Principal Investigator (*if applicable*)
- Research Delegate (*if applicable*)
- Key Personnel (*if applicable*)
- Research Officer/Finance Officer
- Recommendation References (blind) 3 required
- Department Head

### Application Type

- Research priority area in application
- Alternate research priority area in application
- Is the application a resubmission? Select **YES** or **NO**
  - If yes, please include Summary Statement from the previous application
  - Rebuttal Letter (*included in the research plan and does not exceed 2 pages*)
- Indicate yes/no if you agree to allow Breakthrough T1D to share this application with The Leona M. and Harry B. Helmsley Charitable Trust for potential co-funding, under the Breakthrough T1D confidentiality policy
- Clinical classification (*if applicable*)

### Other Support

- Principal Investigator included accurate and complete information regarding all other sources of grant support from the main PI (current and pending), including title, abstract, annual and total amount of the grant, inclusive funding period, and percent effort of the applicant.
- Indicate if any leverage and non-fiscal support

### **Project Descriptions/Abstracts**

- All mandatory text boxes are filled-in

### **Organization Assurances**

- Human Subjects
  - Use of human subject research indicated in the application? (*if applicable*)
  - Uploaded Human Subject Research Plan (*if applicable*)
- Vertebrate Animals
  - Use of animals indicated in the application? (*if applicable*)

### **Proposal Research Plan**

- Introduction to Revised Application (2 pages maximum)
- Research Plan (12 pages maximum)
- Future Plans (2 pages maximum)

### **Additional Attachments**

- Biosketch(es) to be uploaded:
  - Principal Investigator
  - Key Personnel (*if applicable*)
  - Other Faculty Level Investigators: Collaborators, Consultants, Subcontract Investigators, etc. (*if applicable*)
  - Department Head Statement Included (*institutional assurance*)
  - Collaboration Letters Uploaded (*if applicable*)
- *Upload only if applicable:*
  - Human Subject Research Plan (*if applicable*)
  - Protocol Synopsis
  - Resources
  - Supporting Documents
  - Diversity & Inclusion Resource Sheet

### **Budget**

- Followed the Breakthrough T1D budget guidelines outlined in the budget document below
- The maximum total cost requested does not exceed \$200,000 (USD) per year, including 10% indirect costs
- Expenses are consistent with Breakthrough T1D cost principles and sufficient justification is provided (see budget guidelines below)
- No unallowable costs included in the budget (see budget guidelines below)

### **Breakthrough T1D Budget Guidelines**

- **Salaries and Wages** include wages earned by an employee and may include benefits, such as insurance and retirement plans.
  - All personnel listed in the grant (including all key personnel) must be included in the budget and in the personnel justification.
  - If the Principal Investigator is not taking a salary from the grant, then their base salary is \$0.00 but a percent effort and justification must still be provided.

- The percent effort listed in the justification should match the percent effort in the line item budget.
- Confirm that all salaries requested are for personnel at the grantee institution. (see **subcontracts** and **consultants** below).
- **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.
  - Supply costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.
- **Travel Costs** may include any domestic and/or international trips by an employee related to the project and is limited to \$2,000 USD per year.
  - Travel costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.
- **Equipment Costs** can only be requested in year one.
  - Equipment costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.
- **Other Costs** might include items that are not consumable but are needed on a regular basis, such as animal purchases and maintenance changes. Consultants are listed here.
  - **Consultants** are individuals hired to give professional advice or services for a fee. These individuals are typically presented at zero percent effort or as needed (individuals with measurable effort cannot be listed as consultants). The services to be performed by the consultant(s) must be included in the justification along with the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs for each.
  - Other costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.
- **Indirect Costs** cannot exceed 10% of direct costs.

**Subcontracts** are for individuals or entities that contribute to the execution or design of the project, are key personnel on the grant, and/or have measurable percent effort but are not an employee of the grantee institution.

- Subcontracts have the same rules as the main budget (i.e. travel cannot exceed \$2,000, equipment can only be requested in year one, etc.).
- Supplies, travel, equipment, and other costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.

***For all grant mechanisms, the non-exclusive list of non-allowable costs includes:***

- Lobbying
  - Breakthrough T1D 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
- Office Telecommunications
- Advertising Costs
- Patent Applications
- Indirect Cost for Fee for Services, Consultants, and Contractors

For additional information please consult the [Breakthrough T1D website](#), peruse the rest of this document, or review [Breakthrough T1D's pre and post award FAQs](#).

## Early Career Patient-Oriented Diabetes Research Award Application Checklist

### Applicant Information

- Has an MD, MD-PhD, or DO from an accredited institution at award activation
- Has received their first faculty level appointment less than 5 years before submission date
- Holds an appointment or joint appointment in a subspecialty of clinical medicine and conducts human clinical research
- The applicant's institution is a nonprofit or academic entity
- The Principal Investigator is devoting at least 75% of their time and effort on type 1 diabetes related research projects during the period of the award.

### Contacts

- Principal Investigator Biosketch is up to date within profile

*Contact information is provided for:*

- Principal Investigator
- Co-Principal Investigator (if applicable)
- Research Delegate (if applicable)
- Key Personnel (if applicable)
- Research Officer/Finance Officer
- Recommendation References (blind) 3 required (sponsor cannot be a reference)
- Mentor/Sponsor
  - The Sponsor is affiliated full-time with an accredited institution and agrees to supervise the applicant's training

### Application Type

- Research priority area in application
- Alternate research priority area in application
- Is the application a resubmission? Select **YES** or **NO**
  - If yes, please include Summary Statement from the previous application
  - Rebuttal Letter (*included in the research plan and does not exceed 2 pages*)

- Indicate yes/no if you agree to allow Breakthrough T1D to share this application with The Leona M. and Harry B. Helmsley Charitable Trust for potential co-funding, under the Breakthrough T1D confidentiality policy
- Clinical classification (if applicable)

#### **Other Support**

- Completed only for the Sponsor
- Indicate if any leverage

#### **Project Descriptions/Abstracts**

- All mandatory text boxes are filled-in

#### **Organization Assurances**

- Human Subjects
  - Use of human subject research indicated in the application? *(if applicable)*
  - Uploaded Human Subject Research Plan *(if applicable)*
- Vertebrate Animals
  - Use of animals indicated in the application? *(if applicable)*

#### **Proposal Research Plan**

- Introduction to Revised Application (2 pages maximum)
- Research Plan (12 pages maximum)
- Future Plans (2 pages maximum)

#### **Milestones and Timelines**

- Milestone descriptions and projected completion dates have been added, **please enter a value of '0'**

#### **Additional Attachments**

- Biosketch(es) to be uploaded:
  - Principal Investigator
  - Key Personnel (if applicable)
  - Other Faculty Level Investigators: Collaborators, Consultants, Subcontract Investigators, etc. (if applicable)
  - Department Head Statement Included (institutional assurance)
  - Collaboration Letters Uploaded (if applicable)
- *Upload only if applicable:*
  - Human Subject Research Plan (if applicable)
  - Protocol Synopsis
  - Resources
  - Supporting Documents
  - Diversity & Inclusion Resource Sheet

#### **Budget**

- Followed the Breakthrough T1D budget guidelines (see below)

- The maximum total cost requested does not exceed \$200,000 (USD) per year, including 10% indirect costs
- Expenses are consistent with Breakthrough T1D cost principles and sufficient justification is provided (see budget guidelines below)
- No unallowable costs included in the budget (see budget guidelines below)

### **Breakthrough T1D Budget Guidelines**

- **Salaries and Wages** include wages earned by an employee and may include benefits, such as insurance and retirement plans.
  - All personnel listed in the grant (including all key personnel) must be included in the budget and in the personnel justification
  - If the Principal Investigator is not taking a salary from the grant, then their base salary is \$0.00 but a percent effort and justification must still be provided.
  - The percent effort listed in the justification should match the percent effort in the line item budget.
  - Confirm that all salaries requested are for personnel at the grantee institution. (see **subcontracts** and **consultants** below).
- **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.
  - Supply costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.
- **Travel Costs** may include any domestic and/or international trips by an employee related to the project and is limited to \$2,000 USD per year.
  - Travel costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.
- **Equipment Costs** can only be requested in year one.
  - Equipment costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.
- **Other Costs** might include items that are not consumable but are needed on a regular basis, such as animal purchases and maintenance changes. Consultants are listed here.
  - **Consultants** are individuals hired to give professional advice or services for a fee. These individuals are typically presented at zero percent effort or as needed (individuals with measurable effort cannot be listed as consultants). The services to be performed by the consultant(s) must be included in the justification along with the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs for each.
  - Other costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.
- **Indirect Costs** cannot exceed 10% of direct costs.

**Subcontracts** are for individuals or entities that contribute to the execution or design of the project, are key personnel on the grant, and/or have measurable percent effort but are not an employee of the grantee institution.

- Subcontracts have the same rules as the main budget (i.e. travel cannot exceed \$2,000, equipment can only be requested in year one, etc.).
- Supplies, travel, equipment, and other costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.

***For all grant mechanisms, the non-exclusive list of non-allowable costs includes:***

- Lobbying
  - Breakthrough T1D 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
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- Office Telecommunications
- Advertising Costs
- Patent Applications
- Indirect Cost for Fee for Services, Consultants, and Contractors

For additional information please consult the [Breakthrough T1D website](#), peruse the rest of this document, or review [Breakthrough T1D's pre and post award FAQs](#).

## Industry Discovery & Development Partnerships (IDDP) Program Application Checklist

### **Applicant Information**

- Company is a registered business

### **Contacts**

- Principal Investigator Biosketch is up to date within profile

*Contact information is provided for (e-mail addresses must be unique for each role):*

- Principal Investigator (PI): Responsible for the scientific or technical aspects of the grant and for day-to-day management of the project. The PI is also responsible and accountable to his/her Company for the proper conduct of the grant, including the submission of all required reports. For IDDP applicants, the PI has usually been the Chief Executive Officer (CEO) or the equivalent, but this can be left to the Company's discretion.
- Co-Principal Investigator(s), if applicable
- CEO, if different than the Principal Investigator
- Finance Officer



- Research Officer: Responsible for submitting the full application
- Other key personnel, if applicable

#### **Application Type**

- Indicate research priority area.
- Indicate alternate research priority area.
- Is the application a resubmission? Select **YES** or **NO**.
  - If yes, please include Summary Statement/Critique Book from the previous application, if applicable.
  - If yes, please include the Rebuttal Letter, if applicable.
- Do you agree to allow Breakthrough T1D to share this application with The Leona M. and Harry B. Helmsley Charitable Trust for potential co-funding, under the Breakthrough T1D confidentiality policy? Select **YES** or **NO**.
- Indicate clinical classification, if applicable.
- Indicate name(s) of institutional review board(s).

#### **Other Support**

- Include accurate and complete information regarding all other sources of grant support (current and pending), from the Principal Investigator, including title, abstract, annual and total amount of the grant, inclusive funding period, and percent effort of the applicant, if applicable.
- Include a description of the company’s fundraising plans.
- Company in-kind contributions (“leverage”). Please provide a brief description of the in-kind contribution, and the estimated value over the course of the proposed research project.
- External sources of support (i.e., non-Breakthrough T1D grant funding).

#### **Project Descriptions/Abstracts**

- Complete all mandatory text boxes.
- Include a description of the developmental (regulatory and commercialization) plan for the product being investigated.

#### **Organization Assurances**

- Indicate if study involves human subjects or vertebrate animals.
- Appropriate institutional review board (IRB) and/or animal care and use committee approval forms, if available at the time of submission.

#### **Proposal Research Plan**

- Download and complete the research plan template from RMS and then upload it into RMS.
- 12 pages maximum unless noted otherwise on RFA call document.

#### **Milestones and Timelines**

- Please enter a Milestone Description and Projected Completion Date for each milestone.

#### **Required Attachments**

- Human Company Profile

- Financial statements: audited financial statements, or if available, the most recent audit report
- Intellectual Property and info disclosure
- Biosketches: Upload for PI, any Co-PIs, faculty-level investigators including collaborators and consultants, key personnel, and Subcontract PI / Investigators

#### **Additional Attachments**

- Human Subject Research Plan, if applicable
- Protocol Synopsis and full protocol, if available
- Other Supporting Documents, including (a) description of collaborative arrangements, e.g. a letter of confirmation from each collaborator, summary of the collaborator's anticipated key contributions; and (b) additional relevant documents, e.g., manuscripts, addendums
- Diversity & Inclusion Resource Sheet

#### **Budget**

- Include the total project budget requested from Breakthrough T1D. Provide sufficient budget justifications for budget categories and line items.
- Ensure investigator(s) and key personnel are listed as salary line items and percent effort is indicated.
- No unallowable costs. Examples of unallowable costs include general and administrative costs, rent, and indirect costs.
- **Matched funds (or matched resources):** Include a budget for the company's contribution to the project, including a description of how the matched funds will be solely used for the project.
- **Subcontractor budget, if applicable:** Provide full budget and justification details equivalent to the main budget.

#### **Breakthrough T1D Budget Guidelines**

- **Salaries and Wages** include wages earned by an employee and may include benefits, such as insurance and retirement plans.
  - All personnel listed in the grant (including all key personnel) must be included in the budget and in the personnel justification.
  - If the Principal Investigator is not taking a salary from the grant, then their base salary is \$0.00, but a percent effort and justification must still be provided.
  - The percent effort listed in the justification should match the percent effort in the line-item budget.
  - Confirm that all salaries requested are for personnel at the grantee institution (see **subcontracts** and **consultants** below).
- **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.
  - Supply costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.
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- Travel costs should be broken down into line items under the corresponding budget categories. Separate justifications should be provided for each line item.
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- Indirect Cost for Fee for Services, Consultants, and Contractors

For additional information please consult the [Breakthrough T1D website](#), peruse the rest of this document, or review [Breakthrough T1D's pre and post award FAQs](#).

## 5. Administrative Resources

All awards that were activated or renewed after March 1, 2014 are subject to the Breakthrough T1D Terms and Conditions that were signed off on upon Activation or Renewal of your award in [RMS360](#). Click the link to view the most recent version of [BreakthroughT1D's Terms and Conditions](#). Please note, Breakthrough T1D's terms are non-negotiable. The Terms and Conditions that your institution executed can be found within each individual award in the Research Officer portal in [RMS360](#). For assistance in locating your award's Terms and Conditions, please see the [RMS360 Pre and Post Award FAQs](#) or contact your [Breakthrough T1D Research Administrator](#).

Please review the following administrative procedures in order to assist you with managing your grant in [RMS360](#) in the most effective manner.

For questions regarding any administrative procedures, please see the [RMS360 Pre and Post Award FAQs](#) or contact your [Breakthrough T1D Research Administrator](#).

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## 5.1. RMS360

### 5.1.1 Overview

All Breakthrough T1D Grants are managed through [\*\*RMS360\*\*](#), a web-based grants management system designed to facilitate the grantee's submission of materials from Activation through Closeout. Additional requirements outside of the Breakthrough T1D Terms and Conditions will be clearly indicated in the special notes section of the Award Notification email, Award Activation Confirmation email, and/or Award Renewal Confirmation email.

All reports, including Activations, Renewals, Progress Reports, and Expenditure Reports must be submitted in [\*\*RMS360\*\*](#), unless otherwise indicated. Reminder emails will be sent through [\*\*RMS360\*\*](#) in advance of reporting deadlines. In addition, unless otherwise instructed by your [\*\*Breakthrough T1D Research Administrator\*\*](#), all other grant materials (i.e. IRB/IACUC, No Cost Extension, Publications, Budget Updates, etc.) should be submitted via [\*\*RMS360\*\*](#).



## 5.1.2 Login Information

Each grant managed in [RMS360](#) has three designated users: the Principal Investigator (PI), the Research Officer (RO), and the Financial Officer (FO). Details regarding the roles and responsibilities of the Breakthrough T1D grantees can be found in [Grantee Roles and Responsibilities](#).

Breakthrough T1D will email an ‘Award Notification’ and ‘Award/Activation Instructions’ to the PI and RO when an award has been approved for funding. The ‘Award/Activation Instructions’ will contain information about logging into [RMS360](#) to activate your award.

In order to login, go to [RMS360](#), and enter your username and password. If you are unsure of your password, please enter your username, and click “Forgot Your Password.” An email will be sent to the associated email address containing your password. Please note that usernames are generated based on the email addresses provided at application.

Logging into [RMS360](#) and accepting the Breakthrough T1D Terms and Conditions is the first step to activate your newly funded grant. For additional instructions for logging in, please see the [RMS360 Pre and Post Award FAQs](#).

## 5.2. Grantee Roles & Responsibilities

The roles and responsibilities of Breakthrough T1D Grantees are as follows:

### 5.2.1 Principal Investigator (PI)

The Principal Investigator is designated by the Grantee Institution and is the individual responsible for the scientific or technical aspects of the grant and for day-to-day management of the project. The PI is responsible and accountable to his/her Institution/Organization for the proper conduct of the grant, including the submission of all required reports.

#### **RMS360**

The Principal Investigator has access to all reporting materials in [RMS360](#) for his/her grant(s) with the exception of the annual Expenditure Report. The PI may complete most sections of the Activation and Renewal before submitting these items to the Research Officer. In addition, the PI will complete and submit other reporting items in [RMS360](#) as needed throughout the lifecycle of the award such as Scientific Progress Reports and Ethical Renewals. For more information on the appropriate approver for each report please review [Monitoring and Reporting Procedures](#).

### 5.2.2 Financial Officer (FO)

The Financial Officer is designated by the Grantee Institution and is responsible for the proper accounting of grant funds. In this role, the individual is required to complete and certify the required annual Expenditure Reports.

#### **RMS360**

The Financial Officer is designated by the Grantee Institution and has access to Expenditure Reports for assigned grants. In this role, the FO is required to complete the ‘actuals’ column and the Carry Forward breakdown in the Expenditure Report and submit the report to the Research Officer.



For more information on the appropriate approver for each report please review [Monitoring and Reporting Procedures](#).

### 5.2.3 Research Officer (RO)

The Research Officer is designated by the Grantee Institution and is responsible for the proper administration of the grant including, but not limited to, overseeing the submission of the grant Activation, Renewal(s), Expenditure Reports and additional materials required according to Breakthrough T1D's Administrative Procedures (i.e. Budget Updates, No Cost Extension requests, etc.). In addition, the RO is required to complete the payment details for Activations and Renewal(s), certify that all information submitted is accurate, approve the budget for each year and make the final submission to Breakthrough T1D.

#### **RMS360**

The Research Officer has access to all reporting materials in [RMS360](#) for the RO's assigned grant(s) once they have been submitted to the RO by either the PI or the FO. For more information on the appropriate approver for each reporting type please review [Monitoring and Reporting Procedures](#).

It is the responsibility of the Research Officer to ensure that all contact information for the grant's designated PI, FO and RO is correct. For instructions on how to change a user's contact information in RMS 360 please see the [RMS360 Pre and Post Award FAQs](#).

### 5.2.4 Research Delegate

The Research Delegate is designated by the Principal Investigator to assist with all required PI submission.

#### **RMS360**

The Research Delegate has access to all reporting materials in [RMS360](#) for his/her assigned grant(s) with the exception of the annual Expenditure Report. The Research Delegate may complete most sections of the Activation and Renewal. In addition, the Research Delegate can complete other reporting items in [RMS360](#) as needed throughout the lifecycle of the award such as Scientific Progress Reports and Ethical Renewals. The Research Delegate cannot submit any items in RMS360. For more information on the appropriate approver for each report please review [Monitoring and Reporting Procedures](#).

### 5.2.5 Technology Transfer Officer (TTO)

The Technology Transfer Office contact is designated by the Grantee Institution and is the individual responsible for reporting all Intellectual Property to Breakthrough T1D.

#### **RMS360**

The Technology Transfer Office contact is added to an award at the time of Activation. The purpose of this role is to populate and track Intellectual Property of grants that he/she is assigned in [RMS360](#). The TTO will be able to add/view the IP of the grants they are assigned.

## 5.3. Ethical Oversight

### Human Subjects Research

For a project that includes human subject research, please review the [Human Subject Research Guidelines](#).

### 5.3.1. Human Subjects & Animal Welfare

All projects with human subjects and/or animal research must have up-to-date Ethical approval documentation at all times for all associated sites and must provide Breakthrough T1D with copies of all approval documentation.

#### Deadlines

All ethical approval documents must be submitted at the time of Activation. Renewals of expired Ethicals may be uploaded on an ongoing basis as the documents expire or at the time of Renewal or No Cost Extension request. All ethical documentation must be current at the time of renewal and at the end date of the grant. There cannot be any gap in ethical coverage during the lifetime of the grant. If the award is a clinical study, please contact the appropriate [Breakthrough T1D Research Administrator](#) as approval may not be required upon Activation. RMS360 will send the PI email reminders when an Ethical is due to expire.

#### Authorized Personnel

It is the responsibility of the PI to ensure that Breakthrough T1D receives all required, up-to-date documentation throughout the duration of the project.

#### Requirements

For all projects that require IRB/EC review, the PI must provide:

- The most recent approval letter from the institutional IRB/EC.
- The most recent approval Study Protocol submitted to the institutional IRB for review.
- The most recent approval of the informed consent documents associated with a given protocol (if applicable).

Any changes to these documents should be submitted to Breakthrough T1D as approved. In the event that the IRB/EC has determined that the study is exempt, the documentation demonstrating this designation must be submitted.

Ethical approval forms submitted in a language other than English require a cover letter in English on the institution's letterhead and signed by the grantee's department head verifying the content of the approval form and its expiration date.

Current IRB/EC Ethical approval forms must be submitted via RMS360 with Activation materials and IRB/EC Renewals may be submitted upon expiration, at Renewal or at the time of a No Cost Extension request. In an active grant, new or renewed Ethicals should be uploaded in RMS360 in the 'Active Grants and Renewal' tab in the PI portal by clicking the blue button that reads 'Ethicals' for the corresponding grant key. Grantees are required to provide additional verification that the Ethical approval is applicable and specific to the Breakthrough T1D award in question. (A checkbox for this purpose is provided to Grantees in RMS360).

### **International Institutions**

International institutions are required to follow the Breakthrough T1D guidelines above. If an international ethical does not expire and is approved for the life of the grant, please enter the grant end date as the expiration date.

### **Clinicaltrials.gov**

Registration should be no later than 21 days after the first subject is enrolled.

## **5.3.2 Confidentiality**

### **Deadline**

Most grant materials submitted to Breakthrough T1D are for internal Breakthrough T1D use only. Exceptions include the Lay Abstract submitted at the time of Application and the Web Progress Reports, submitted on an annual basis with the Annual and Final Progress Report.

### **Authorized Personnel**

It is the responsibility of the PI to ensure the appropriate Lay information is recorded in the Lay Abstracts and annual and final Web Progress Report(s).

### **Requirements**

When completing the Lay Abstract and annual Web Progress Report(s) in [RMS360](#) you will be prompted to acknowledge (in a checkbox) that you are aware this information may be shared with the public. In these sections, grantees should not include any data that is not meant for public disclosure. If you have any concerns or questions regarding inclusion of information in a particular report, please contact the appropriate [Breakthrough T1D Staff](#) prior to final submission in [RMS360](#). For more information on where the Lay information is recorded please review [Monitoring and Reporting Procedures](#).

The Annual and Final Progress Report requires submission of a Scientific Progress Report, Website (Lay) Progress Report, and any associated Publications, Abstracts, or Presentations. In an active grant, the Annual Progress Report can be found in [RMS360](#) in the 'Active Grants and Renewal' tab in the PI portal by clicking on the blue button that reads 'Post Award Reports' for the corresponding grant key.

## **5.3.3 Conflict of Interest**

### **Deadline**

In the interest of maintaining objectivity in research, Breakthrough T1D must ensure that its grant processes are free from any conflicts of interest. Please notify Breakthrough T1D prior to accepting the Terms and Conditions as soon as you are made aware of the specific conflict of interest.

### **Authorized Personnel**

Depending on the type of conflict, the PI, RO or FO should notify Breakthrough T1D of the conflict.

### **Requirements**

Organizations/Institutions that have identified conflicts of interest as they relate to Breakthrough T1D funded research should report these conflicts of interest, in writing, to the appropriate [Breakthrough T1D Research Administrator](#).

### 5.3.4 Scientific & Financial Misconduct

#### **Deadline**

Agreeing to the Breakthrough T1D Terms and Conditions (read and confirmed by the Organization/Institution at the time of Activation) effectively acknowledges that the Institution has established policies and procedures for scientific and financial misconduct. Please notify Breakthrough T1D as soon as scientific or financial misconduct occurs.

#### **Authorized Personnel**

Depending on the type of misconduct, the RO or FO should notify Breakthrough T1D of the conflict.

#### **Requirements**

Should scientific or financial misconduct occur, the Organization/Institution must notify the appropriate [Breakthrough T1D Research Administrator](#), 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.

### 5.3.5 US Economic Sanctions, Anti-Terrorism Laws & Anti-Money Laundering Laws

See Breakthrough T1D Terms and Conditions.

### 5.3.6 Funding Provider and not Sponsor

See Breakthrough T1D Terms and Conditions.

## 5.4. Payment

### 5.4.1 Payment Method

Domestic payments are made via Electronic Fund Transfer (EFT) and International payments are made via Wire Transfer unless otherwise specified. Should a check be issued (in extenuating circumstances), checks will be made payable to an Institution, University, Company, Fund, or Equivalent Organizational Entity. Under no circumstances will Breakthrough T1D make payment to an individual, whether that person is the Principal Investigator or an individual within the Grantee Institution.

All international awards are issued in USD and all payments are processed in USD. Breakthrough T1D is not liable for exchange rate fluctuation. All invoices and Expenditure Reports submitted to Breakthrough T1D must be denominated in USD.

#### 5.4.1.1 Required Payment Details for Domestic Grantees

For domestic grants, the Research Officer is required to provide the following information:

- Payee Name
- Depository (Bank) Name
- Depository (Bank) Address
- Street

- City
- State
- Zip Code
- Routing/ABA #
- Account #
- Institution/organization's EIN

### 5.4.1.2 Required Payment Details for International Grantees

For international grants, the Research Officer is required to provide the following information:

- Payee Name
- Bank Name
- Bank Address
- Sort Code
- Swift/BIC Code
- Account #
- IBAN

### 5.4.1.3 Required Payment Details for All Grantees

A PDF of a letter from the Institution's bank certifying the payment details entered in [RMS360](#) is required for all grants. This letter must be on the bank's official letterhead and signed by a bank official. If the letter is in a language other than English, it must be accompanied by a letter (in English) from the Grantee Institution, on the Grantee Institution's official letterhead and signed by an Institutional Official, translating the certification. These letters must be uploaded in [RMS360](#) in the RO profile and linked to the Payment Details section of the Activation and Renewal(s). For instructions on how to upload and link these letters please see the [RMS360 Pre and Post Award FAQs](#).

## 5.4.2 Payment Schedules & Terms

Payment schedules and terms differ by award type and grant. The grantee will be made aware of payment terms at the time of funding.

Payment categories and their associated award types are as follows:

### 5.4.2.1 One Payment per Year

Applicable to non-clinical grants up to \$250,000 (total yearly budget).

#### **Payment Terms**

First Year: One payment in the amount of the approved Year 1 budget made upon grant Activation following successful completion and approval of all required Activation materials.

- Renewal years: One payment in the amount of the approved yearly budget made upon successful completion and approval of the yearly Renewal, Annual Progress Report and previous year's Expenditure Report and up to date IRB/IACUC approvals if applicable.

- Final year: Two payments. First payment in the amount of the approved yearly budget less 10% of the award total made following successful completion and approval of yearly Renewal, Annual Progress Report and previous year's Expenditure Report. Final payment of 10% of the award total or the remaining balance based on Expenditures, whichever is least, upon completion and approval of all Final Reports.
- Holding: Should any required documentation (Renewals, Expenditure Reports, etc.) become past due, all payments will be held until those overdue items have been submitted and approved.

### 5.4.2.2 Quarterly Payments

Applicable to non-clinical grants with Quarterly Progress Reports. These grant types embody cooperative development of a research plan, quarterly reporting on milestones and interaction with Breakthrough T1D Scientists prior to and during the award period. The budget and duration of funding are variable and continued funding is based on satisfactory effort and quarterly progress on milestones.

#### **Payment Terms**

Payments are made quarterly and are tied to completion and approval of a Quarterly Progress Report (initial payment made at grant Activation).

- First year: Payment made upon grant Activation following successful completion and approval of all required Activation materials and subsequently upon Breakthrough T1D receipt and approval of Progress Reports.
- Renewal years: Payments made upon Breakthrough T1D receipt and approval of the yearly Renewal and Quarterly/Annual Progress Reports.
- Final year: The final year will be split into five payments. Payments will be made the same as Renewal years except the final payment will be held until completion and approval of all Final Reports.
- Holding: Should any required documentation (Renewals, Expenditure Reports, etc.) become past due, all payments will be held until those overdue items have been submitted and approved.

### 5.4.2.3 Semi-Annual Payments

Applicable to non-clinical grants with Semi-Annual Progress Reports. These grant types embody cooperative development of a research plan, Semi-Annual Reporting on milestones and interaction with Breakthrough T1D scientists prior to and during the award period. The budget and duration of funding are variable and continued funding is based on satisfactory effort and progress on milestones.

#### **Payment Terms**

Payments are made semi-annually and are tied to completion and approval of Semi-Annual Progress Reports (initial payment made at grant Activation).

- First year: Payment made upon grant Activation following successful completion and approval of all required Activation materials and subsequently upon Breakthrough T1D receipt and approval of Progress Reports.
- Renewal years: Payments made upon Breakthrough T1D receipt and approval of the yearly Renewal and Semi-Annual/Annual Progress Reports.
- Final year: The final year will be split into three payments. Payments will be made the same as Renewal years except the final payment will be held until completion and approval of all Final Reports.
- Holding: Should any required documentation (Renewals, Expenditure Reports, etc.) become past due, all payments will be held until those overdue items have been submitted and approved.

#### 5.4.2.4 Clinical Milestone Based Payments

Applicable to all clinical grants with milestone timelines.

##### **Payment Terms**

Payments are tied to a scientific milestone. Amounts for each milestone are determined prior to award Activation. An invoice must be submitted to the appropriate [Breakthrough T1D Research Administrator](#) via email for each milestone achieved. Both the Scientific and Breakthrough T1D Administrative personnel will review and approve submitted invoices.

Invoices must include the following:

- Name of Principal Investigator
- Breakthrough T1D Grant Key
- Milestone Description
- Milestone Amount
- Milestone Completion Date (the date the science was complete NOT the date the invoice was created)

Breakthrough T1D does not require invoices for the initial milestone related to start-up fees or any milestones associated with the upload of Ethical approvals and/or submission of Breakthrough T1D required Reports in [RMS360](#).

- First year: Payment made upon grant Activation following successful completion and approval of all required Activation materials and subsequently upon Breakthrough T1D receipt and approval of invoices.
- Renewal years: Payments made upon Breakthrough T1D receipt and approval of invoice.
- Final year: Same as Renewal years, except final payment is held until all Final Reports are submitted and approved in RMS360.



## 5.4.2.5 Invoices per a Contract

Applicable to Contract-based grants.

### **Payment Terms**

Payment schedule and award requirements are described in the award Contract and all payments are tied to an invoice and/or achievement of a milestone as detailed in a Scientific Progress Report, if applicable.

If the first milestone in a Contract Agreement is for payment upon execution of the contract agreement, no invoice is required.

## 5.4.2.6 Other

Applicable to grants that do not fall within categories 4.2.1 – 4.2.5 and have special payment terms as designated in the funding letter in the special notes section.

For additional information, please review our [Monitoring and Reporting Procedures](#).

## 5.5. Cost Considerations

### **Deadline**

Please review the Breakthrough T1D Terms and Conditions prior to submitting the Activation and Renewal materials to ensure your budget is compliant with Breakthrough T1D Cost Principles.

### **Authorized Personnel**

At the time of Activation and Renewal, the PI is responsible for filling out an appropriate budget based on the awarded amount for the budget year and the Breakthrough T1D Terms and Conditions. The yearly budget must be reviewed and approved by the RO prior to submission to Breakthrough T1D.

### **Requirements**

The PI should justify the itemized budget in detail within the budget justification. This information will be reviewed by Breakthrough T1D Scientific and Research Administrative personnel before the Activation and Renewal(s) are approved to ensure cost principle compliance.

See Breakthrough T1D Terms and Conditions for additional information and guidelines relating to cost considerations.

## 5.6. Administrative Requirements

### 5.6.1 Other Support

#### **Deadline**

Personnel contributing to a Breakthrough T1D grant are expected to monitor their total percent effort across all funding (Breakthrough T1D or other) which may not exceed 100%. Other support is entered in the application stage and revised accordingly at the time of Activation and Renewal(s).



### **Authorized Personnel**

The PI on a Breakthrough T1D grant must provide the PI's percent effort on that grant and a listing of all other support with the PI's associated percent effort.

### **Requirements**

The PI should enter the PI's other sources of support within the "My Profile" section at the time of application in [RMS360](#). This should then be updated at the time of Activation/Renewal(s).

## 5.6.2 Change in Research Plan

### **Deadline**

As soon as there is a change in the Research Plan.

### **Authorized Personnel**

The PI or RO should submit any changes in the Research Plan.

### **Requirements**

Any revision to the approved research plan must be approved by Breakthrough T1D Scientific personnel responsible for the oversight of the award. The request must be signed by an Organizational/Institutional official and sent to the appropriate [Breakthrough T1D Research Administrator](#).

## 5.6.3 Unexpended Balances

### **Deadline**

Refunds greater than \$250 must be returned to Breakthrough T1D within 60 days of Expenditure Report due date.

### **Authorized Personnel**

The FO is responsible for submitting the refund.

### **Requirements**

Please contact the appropriate [Breakthrough T1D Research Administrator](#) for the EFT instructions on how to submit the refund back to Breakthrough T1D.

## 5.6.4 Carry Forwards (CF)

### **Deadline**

If an unexpended balance remains at the end of a given grant year for a multi-year grant, Breakthrough T1D may allow the grantee to Carry Forward the funds into the following year.

Automatic and Non-Automatic CF thresholds can be found in the Breakthrough T1D Terms and Conditions.

All Carry Forward requests are made in conjunction with the submission of the annual Expenditure Report. For more information on the annual Expenditure Report see [Expenditure Reporting](#).

### **Authorized Personnel**

The FO must enter the appropriate expenses and CF amount in the Expenditure Report and submit

it to the RO for final approval. The PI does not have access to the Expenditure Report and therefore must work with the FO and RO to enter the justification for the CF request.

### **Requirements**

If there are unexpended balances at the end of a budget year the grantee may request to Carry Forward these unexpended funds. For all CFs, the budget distribution for the requested Carry Forward amount must be entered in the CF tab of the Expenditure Report. In addition, for Non-Automatic Carry Forwards, the institution must answer the questions in the text boxes located at the bottom of the CF tab prior to submitting the Expenditure Report to Breakthrough T1D.

All requested CFs must be approved by Breakthrough T1D Research Administrative and Scientific personnel. Upon completion of Breakthrough T1D review, the institution will receive an email either confirming or denying the CF request.

Breakthrough T1D must receive all Renewal materials and the associated Annual Progress Report (via [RMS360](#)) prior to the Expenditure Report/CF request being considered for approval.

## **5.6.4.1 Carry Forwards for Postdoctoral Fellows and Advanced Postdoctoral Fellows**

See [Breakthrough T1D Terms and Conditions](#) for more information.

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

### **Deadline**

Grants that are eligible to request No Cost Extensions will receive an 'End Date Reminder' via email 90 days prior to the grant end date. This email will contain instructions on requesting an NCE. An official request for a NCE must be submitted through [RMS360](#) no later than 45 days prior to the original end date of the award.

### **Authorized Personnel**

The PI is responsible for completing the scientific portions of the NCE request and the FO and RO are responsible for completing the financial portion of this request.

### **Requirements**

Once the PI receives the 'End Date Reminder', the PI may login to the PI portal in [RMS360](#) and click on the NCE link found in the 'Active Grants and Renewal' tab.

- The PI should download the Progress Report template, complete and upload in the designated area of the NCE activity.
- The PI should also complete the designated NCE questions within the text boxes provided.
- The PI should enter the revised end date in the text box provided.
- The RO/FO should download the Interim Expenditure Report template, complete and upload in the designated area. The Expenditure Report will need to be signed by the appropriate Institutional Official.
- The RO/FO needs to enter the projected budget for the requested NCE period in the text box provided.



The RO must submit the NCE to Breakthrough T1D for Research Administrative and Scientific approval prior to the due date indicated on the end date reminder email. Breakthrough T1D Scientific and Administrative personnel manage project timelines to ensure scientific progress is consistent with Breakthrough T1D's mission and strategic deliverables. NCE requests are, therefore, highly scrutinized. For additional instructions on submitting a no-cost extension request, please see the [RMS360 Pre and Post Award FAQs](#).

Funds remaining at the end of the grant period are not sufficient justification to extend the project period. Submission of a NCE request does not denote that the request will be granted.

If approved, the institution will be notified of the new award end date and any additional revised Reporting requirements during the NCE period via an [RMS360](#) email notification.

See [Reallocation of Funds](#) for information regarding requests to reallocate funds in the final budget period (which includes the NCE).

## 5.6.6 Reallocation of Funds

### **Deadline**

As soon as the PI and/or Grantee Institution is made aware of the Reallocation.

### **Authorized Personnel**

The initial Reallocation request should be made by the PI and/or the RO. If the Reallocation request is approved, the PI must submit the budget update in [RMS360](#) to the RO for final approval.

### **Requirements**

If a PI would like to request a Reallocation of funds over the Breakthrough T1D allowable threshold, they must email a detailed narrative request to the appropriate [Breakthrough T1D Research Administrator](#).

If this request is approved by Breakthrough T1D personnel, a Budget Update activity will be opened in [RMS360](#) for the PI to complete. The PI will be sent an email with the due date for submitting the Budget Update. Once opened, the Budget Update can be found in [RMS360](#) in the 'Active Grants and Renewal' tab in the PI portal. For additional instructions on submitting a Budget Update, please see the [RMS360 Pre and Post Award FAQs](#).

If Breakthrough T1D Administrative and Scientific personnel approve the Reallocation request, the institution will be notified and provided documentation via email confirming the revised budget.

Please see Breakthrough T1D Terms and Conditions for Breakthrough T1D Reallocation thresholds and guidelines.

## 5.6.7 Change in Percent Effort for Key Personnel

### **Deadline**

As soon as the PI and/or Grantee Institution is made aware of the Percent Effort change of Key Personnel.

### **Authorized Personnel**

The PI and RO must complete the Change in Percent Effort request.

### **Requirements**

If the Grantee would like to change the percent effort of Key Personnel beyond the threshold, the Grantee must submit an official written request to Breakthrough T1D. The request must be on institutional letterhead and signed by the PI and an Institutional Official. Requests to change Percent Effort should be submitted via email to the appropriate [Breakthrough T1D Research Administrator](#).

Please see Breakthrough T1D Terms and Conditions for reallocation thresholds for a change in Percent Effort for Key Personnel.

## **5.6.8 Leave of Absence (LOA)**

### **Deadline**

Any leave of absence request, including maternity and paternity leave, must be submitted in writing to Breakthrough T1D within 30 days of the start date of the LOA.

### **Authorized Personnel**

The PI and RO must complete this LOA request.

### **Requirements**

The LOA request must be on institutional letterhead and must include an appropriate justification for the leave of absence, the start and end dates of the LOA, a request to extend the budget period (if applicable), the signature of the PI, and the signature of an Institutional Official. This request should be emailed to the appropriate [Breakthrough T1D Research Administrator](#).

The PI or Grantee Institution may submit a request to extend the budget period in which the LOA occurs so as to allow for scientific progress consistent with the original research plan's timeline. A request to extend the budget period must be included in the LOA request provided to Breakthrough T1D as specified above. The extension cannot exceed the period of time pertaining to the LOA. If applicable, the start date of subsequent budget period will be modified accordingly to reflect the extension. Subsequent budget periods will not be shortened as a consequence of the LOA budget period extension.

## **5.6.9 Transfers**

### **Deadline**

As soon as the PI and/or Grantee Institution is made aware that a PI will be Transferring institutions. Any request from the Principal Investigator to transfer Grantee Institutions must be made in advance of the anticipated start date at the new Institution. \*\* Postdoctoral and Advanced Postdoctoral Fellowships are not eligible for transfers.

### **Authorized Personnel**

The PI must notify the appropriate [Breakthrough T1D Research Administrator](#) of the upcoming Transfer. The PI must then complete the 'Termination' activity and submit it to the RO for final review and submission. The FO and RO are responsible for submitting the financials and refund (if applicable). The PI must complete a transfer application at the new institution and submit it to the RO at the new institution for final approval.



## Requirements

The transfer request should be made by email to the appropriate [Breakthrough T1D Research Administrator](#).

Upon receipt of this request, the [Breakthrough T1D Research Administrator](#) will open a 'Termination' activity in [RMS360](#) to be completed and submitted by the original Grantee Institution and will notify the PI of the due date of this request. Once opened, the 'Termination' activity will be located in [RMS360](#) in the 'Active Grants and Renewal' tab in the PI portal. There will be several questions that the PI and RO will be required to answer. In addition, the RO will need to enter the amount of unexpended funds and agree to relinquish all claims to any unexpended and uncommitted funds remaining in the grant as of the Institution termination date. The appropriate signing authority will need to enter their name, title and the date of execution prior to submitting the 'Termination' activity to Breakthrough T1D. For additional instructions on submitting a 'Termination', please see the [RMS360 Pre and Post Award FAQs](#).

The following items will be required in relation to the Transfer request:

- A Final Expenditure Report from the original Grantee Institution will be required in [RMS360](#) within 60 days of the end date at the original Institution.
- Breakthrough T1D will require a refund for any unexpended funds remaining at the original Grantee Institution within 60 days of the Final Expenditure Report due date.
- If the Transferring award is in its final year and the PI expects to request a No-Cost Extension, the original Grantee Institution will need to complete an NCE request in tandem with the termination activity between 90 – 60 days prior to the end date. Please note that all NCEs need to be approved prior to the transfer taking place.
- A Transfer Grant Application will be opened for the new Grantee Institution to complete and submit in [RMS360](#).
- If the Transfer Grant Application is approved, the PI and RO at the new Grantee Institution will receive an "Award Notification" email and will be asked to complete the Activation in [RMS360](#).

## 5.6.10 Supplements

### Deadline

As soon as the PI and/or Grantee Institution is made aware that a supplement will be requested.

### Authorized Personnel

The PI must notify the appropriate [Breakthrough T1D Research Administrator](#) of the supplement request. The PI must then complete the supplement application and submit it to the RO for final review and submission.

### Requirements

The supplement request should be made by email to the appropriate [Breakthrough T1D Research Administrator](#).



Upon receipt of this request, if approved by Breakthrough T1D Scientific staff, the Breakthrough T1D Research Administrator will open a supplement application in RMS360 to be completed and submitted by the Grantee Institution and will notify the PI of the due date of this application. Once opened, the supplement application will be located in RMS360 in the 'Pending Proposals' tab in the PI portal for the PI to complete and submit to the RO for review and submission to Breakthrough T1D.

## 5.7. Monitoring & Reporting

All reporting should be completed via [RMS360](#) unless otherwise specified by your [Breakthrough T1D Research Administrator](#). For instructions on submitting items in [RMS360](#), please see the [RMS360 Pre and Post Award FAQs](#).

### 5.7.1 Award Activation

#### **Deadlines**

The Award Notification will clearly state the Activation materials deadline as well as the anticipated start date for the grant. Materials are customarily due 1 month prior to the anticipated grant start date.

#### **Authorized Personnel**

The PI and RO both have access to the Activation in [RMS360](#). The PI is expected to contribute to any pertinent sections of the Activation including the Contact Information, IRB/IACUC, Budget, Milestones if applicable and Other Support. Once completed, the PI must submit the Activation to the RO. The RO is required to complete the payment details and has the sole authority to submit the Activation to Breakthrough T1D. The RO is also responsible for approving the budget.

#### **Requirements**

Prior to the start of any grant, all grantees are required to submit Activation materials. The Activation requires submission of the following details including but not limited to: accurate contact information, applicable Ethical approval documentation, projected budget for the funding period, payment details, milestones if applicable and other support information. By submitting the Activation, the grantee accepts the Breakthrough T1D Terms and Conditions for the grant.

The Activation in [RMS360](#) can be found in the 'Active Grants and Renewal' tab in the PI portal. For additional instructions on submitting an Activation, please see the [RMS360 Pre and Post Award FAQs](#).

### 5.7.2 Yearly Progress Reporting and Renewal

#### **Deadlines**

For most multi-year grants, an Annual Progress Report and Renewal are due 30 days prior to the start of each new funding period.

#### **Authorized Personnel**

The PI is expected to complete the Scientific Progress Reports and submit them directly to Breakthrough T1D. The PI is also expected to contribute to any pertinent sections of the Renewal(s) including the Contact Information, IRB/IACUC, Budget, and Other Support. Once completed, the PI

must submit the Renewal to the RO. The Research Officer is required to complete the payment details and has the sole authority to submit the Renewal(s) to Breakthrough T1D. The RO is also responsible for approving the budget.

### **Requirements**

On an annual basis, grantees are required to submit the Annual Progress Report and Renewal (for multi-year grants). The Annual Progress Report requires submission of the Scientific Progress Report, Website Progress Report (Lay audience), and any associated Publications, Abstracts (Lay audience), or Presentations. The Renewal requires submission of the following details: the projected budget and justifications for the new funding period, payment details, and updated other support information.

The Renewal in [RMS360](#) can be found in the 'Active Grants and Renewal' tab in the PI portal. All required Progress Reports can be found in [RMS360](#) in the 'Active Grants and Renewal' tab in the PI portal by clicking the blue button that reads 'Post-Award Reports'. For additional instructions on submitting a Renewal, please see the [RMS360 Pre and Post Award FAQs](#).

## **5.7.3 Final Progress Reporting**

### **Deadlines**

For all grants, a Final Scientific Progress Report is required within 75 days after the end of the grant period. Final Progress Reports are also required for all grants that have been terminated (either by Breakthrough T1D or by the Grantee).

### **Authorized Personnel**

The PI must complete and submit the Final Progress Report in [RMS360](#).

### **Requirements**

All grantees are required to submit a Final Progress Report. The report requires submission of the Scientific Progress Report, Website Progress Report (Lay audience), a link to the public site where data is/will be shared, and any associated Publications, Abstracts (Lay audience), or Presentations.

All required Progress Reports can be found in [RMS360](#) in the 'Active Grants and Renewal' tab in the PI portal by clicking the blue button that reads 'Post-Award Reports'.

## **5.7.4 Additional Progress Reporting**

### **Deadline**

Required reporting in addition to the Annual and Final Progress Reports will be clearly defined in the Award Notification for the individual grant and/or via official correspondence regarding changes to the terms during the life of the grant.

### **Authorized Personnel**

The PI is responsible for submitting all Progress Reports.

### **Requirements**

All required Progress Reports can be found in the in [RMS360](#) in the 'Active Grants and Renewal' tab in the PI portal by clicking the blue button that reads 'Post-Award Reports'.

## 5.7.5 Expenditure Reporting

### **Deadlines**

The Expenditure Report is due within 75 days of the end of each budget period.

### **Authorized Personnel**

The Institution's designated Financial Officer has the authority to complete the Expenditure Report. This report must then be submitted to the Research Officer who has the sole authority to approve the Expenditure Report and submit it to Breakthrough T1D. The PI may relate any necessary Reallocation and/or Carry Forward requests to the Financial and Research Officer; however, the PI does not have access to the Expenditure Report in [RMS360](#).

### **Requirements**

The Expenditure Report outlines financial expenditures of Breakthrough T1D funds spent for the given budget period, and must follow the Breakthrough T1D approved budget for the grant budget period. A grant's expenditures must also follow the Breakthrough T1D [Cost Principles](#). Breakthrough T1D does not require a copy of the general ledger as a component of the Expenditure Report; however, Breakthrough T1D reserves the right to request a copy of the general ledger if deemed necessary. All Expenditure Reports can be found in the in the FO portal in the 'Expenditure Reports' tab in [RMS360](#).

## 5.7.6 Intellectual Property, Invention Reporting, & Royalties

Effective for all grants activated on or after March 1, 2014

### **Deadline**

Materials associated with Intellectual Property, Invention Reporting, & Royalties for any active grants should be given to Breakthrough T1D as soon as the Grantee Institution is made aware of these materials.

### **Authorized Personnel**

The PI and RO have access to login to [RMS360](#) and upload related materials.

### **Requirements**

Please upload materials in [RMS360](#). This can be uploaded in the 'Active Grants and Renewal' tab in the PI portal by clicking on the blue button that reads 'Intellectual Property' or in the transactions tab of the RO portal.

Materials associated with Intellectual Property, Invention Reporting, & Royalties for any closed grants should be emailed to the appropriate [Breakthrough T1D Research Administrator](#).

See Breakthrough T1D Terms and Conditions for updated Intellectual Property, Invention Reporting & Royalty information.

### **Intellectual Property, Invention Reporting, & Royalties for awards that activated prior to 7/1/2012**

Invention disclosures, patent applications, patent allowances and the execution of IP Transfer Agreements (including but not limited to the licensing/sublicensing, sale, transfer or other



commercial utilization of a Breakthrough T1D supported invention) to use inventions protected by such patent applications relating to any invention made with the support, in whole or in part, of Breakthrough T1D research or training awards, must be reported within 60 days via RMS360. The report shall include a brief description of the invention, its 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.

Grantees are required to 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 years after the expiration of the Breakthrough T1D grant in question. The grantee agrees to 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 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.

Patent applications and the execution of license agreements to use inventions protected by such patent applications relating to any invention made with the support, in whole or in part, of Breakthrough T1D research or training awards, must be reported within 60 days via RMS360.

Grantees are required to report patent applications and/or the execution of licensing agreements (as stated above) to Breakthrough T1D for a period of three years after the expiration of the Breakthrough T1D grant in question.

Unless otherwise indicated or requested by the grantee institution, title to any invention will reside with the grantee institution. If a grantee institution has no established patent policy or procedure for administering inventions, Breakthrough T1D reserves the right to determine the disposition of invention rights, including the right to take title to an invention or patent and develop technologies/products resulting from the Breakthrough T1D-funded research in the event that the grantee institution elect not to patent and pursue these developments. In this event, it is Breakthrough T1D's policy to request that the institution execute appropriate assignments in favor of Breakthrough T1D (which assignments shall be prepared by Breakthrough T1D at its own expense) for purposes of patenting the results of the Breakthrough T1D-funded research.

In acknowledgement of Breakthrough T1D's support, net royalties resulting from the commercialization of discoveries made with Breakthrough T1D support will be shared with Breakthrough T1D. The portion of royalties to be shared with Breakthrough T1D shall be determined on a case-by-case basis in accordance with the policies of the grantee institution and will be based on the relative contribution of Breakthrough T1D funding to the overall project. Net royalties shall mean gross royalties and other licensing payments less administrative, licensing, legal, and other reasonably related expenses. Upon request, the grantee institution will provide Breakthrough T1D with financial information adequate to establish and document the amount of net royalties received.



No patent or patent application will be abandoned without first notifying the Research Department of Breakthrough T1D and giving Breakthrough T1D the opportunity to take title to or continue the patent/patent application at Breakthrough T1D's own expense. The grantee institution will notify Breakthrough T1D at least ninety (90) days prior to any abandonment and reporting requirements.

In making decisions whether to continue ongoing grants or whether to award additional grants to a researcher or his/her institution, Breakthrough T1D will consider whether the institution has honored the above policy.

Grantees are required to indicate in their renewal progress reports and close-out final progress reports if any inventions were made during the funding period.

### **Intellectual Property, Invention Reporting, & Royalties for awards that activated from 7/1/12-3/31/13**

Intellectual Property, Invention Reporting, & Royalties  
Effective for all grants activated on or after July 1, 2012

The mission of Breakthrough T1D is to find a cure for diabetes and its complications through the support of research. In furtherance of this mission, Breakthrough T1D 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 directly or indirectly, in whole or in part, from Breakthrough T1D. By accepting funding from Breakthrough T1D, the Research Institution agrees that it is bound by all terms and conditions specified in this Policy.

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

As between Breakthrough T1D and the Research Institution, the Research 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 Research 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 Breakthrough T1D (collectively, the "Research Results"). To the extent that the Research Institution's own policies permit individual Investigators to own any right, title or interest in any Research Results, the Research Institution shall ensure that each Investigator complies with the provisions of this Policy with respect to such Research Results.

The Research Institution shall require any subcontractor that it engages to conduct research using funding provided by Breakthrough T1D to agree to be bound by this Policy to the same extent as the Research Institution is bound. The Research Institution shall provide a copy of this Policy to all such subcontractors.

The Research 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 and development purposes related to the diagnosis, cure, treatment and/or prevention of diabetes and its complications.

The Research Institution understands that the Research Results should be used for the greatest possible public benefit, and acknowledges the potential limiting effect that exclusive licenses could have on further research, unanticipated uses, and future commercialization efforts and markets. Accordingly, the Research Institution shall not transfer, sell, license, assign, or otherwise grant any party the right to use or practice any of the Research Results on an exclusive basis (whether for research, development, commercial or other purposes) in the absence of a separate written agreement from Breakthrough T1D authorizing an exclusive grant of rights, which authorization shall not be unreasonably withheld. The Research Institution shall make any third party to whom it transfers, sells, licenses, assigns, or otherwise grants any rights in any Research Results aware of this prohibition and of the rights of Breakthrough T1D hereunder.

### 5.7.6.2 Other Intellectual Property of the Research Institution

This Policy does not apply to any patents, copyrights, trademarks or other intellectual property of the Research Institution that was not developed in whole or in part under Breakthrough T1D funding.

### 5.7.6.3 Invention Disclosures

The Research Institution shall disclose to Breakthrough T1D within 60 days all potentially patentable inventions that are conceived or first actually reduced to practice by the Research Institution or any of its Investigators during the course of carrying out any research using funding provided directly or indirectly, in whole or in part, by Breakthrough T1D (each an “Invention”). The Research Institution shall make such disclosure via RMS360. The report shall include a brief description of the invention, its 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.

### 5.7.6.4 Patents

As between Breakthrough T1D and the Research Institution, the Research Institution will have the first right to pursue patent protection for Inventions. In the event that the Research 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 Research Institution shall promptly inform Breakthrough T1D of such decision and at Breakthrough T1D’s request the Research Institution shall assign all rights in such Invention in such jurisdiction to Breakthrough T1D. Breakthrough T1D may also require the Research Institution to assign to Breakthrough T1D all rights in any Invention for which Breakthrough T1D reasonably determines the Research Institution is not diligently pursuing patent protection; provided however that prior to any such assignment Breakthrough T1D shall consult with the Research Institution regarding the potential patentability and commercial potential of such Invention, and the Research Institution shall have a reasonable opportunity to commence to



diligently pursue patent protection for such Invention in lieu of assigning such Invention to Breakthrough T1D.

The Research 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.

### 5.7.6.5 Commercialization

Upon the disclosure of a new Invention, the Research Institution shall take appropriate steps to commercialize such Invention in a timely fashion, but within three years of disclosure, either itself or through one or more licensees, in the field of diagnosing, curing, treating, and/or preventing diabetes and its complications. The Research Institution shall ensure that all licenses of commercial rights in or to any Invention require the licensee to diligently pursue commercialization of such Invention and specify objective milestones and benchmarks so that the licensee's progress toward commercialization can be assessed and monitored.

If Breakthrough T1D determines in good faith, after consulting with the Research Institution, that the Research Institution has not itself or through one or more licensees diligently pursued commercialization of any Invention in the field of diagnosing, curing, treating, and/or preventing diabetes and its complications within three years of Invention disclosure, then at Breakthrough T1D's request the Research Institution shall meet with Breakthrough T1D to discuss a commercialization plan for the invention. If the Research Institution is unable to commercialize the Invention within the timeframe determined in the commercialization plan, then at Breakthrough T1D's request the Research Institution shall assign all rights in such Invention to Breakthrough T1D, unless the Research Institution can show reasonable cause as to why it should retain title to such Invention.

### 5.7.6.6 Assignment of Patents to the Breakthrough T1D; Commercialization by the Breakthrough T1D

In the event of an assignment to Breakthrough T1D of rights in any Invention as provided in this Policy, the Research 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 assignment. After the effective date of any such assignment, as between the Research Institution and Breakthrough T1D, Breakthrough T1D shall be solely responsible for all costs associated with filing, prosecuting and maintaining such patent.

In the event that Breakthrough T1D commercializes a product the making, use, sale or import of which would have infringed a valid claim of any such patent absent the assignment to Breakthrough T1D, Breakthrough T1D shall negotiate in good faith with the Research Institution a reasonable



royalty rate that will be payable to the Research Institution based on sales of such product. In addition, in the event that Breakthrough T1D's making, use, sale or import of any product would infringe a valid claim of any patent claiming an Invention that is owned by the Research Institution and that is not assigned to Breakthrough T1D, then the Research 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 such Invention to the extent reasonably necessary to commercialize such product. In the event that Breakthrough T1D's making, use, sale or import of any product would infringe a valid claim of any patent or patent application claiming an invention that is owned by the Research Institution and that was not funded directly or indirectly, in whole or in part, by Breakthrough T1D, then the Research Institution shall reasonably negotiate with Breakthrough T1D with respect to any rights under such patent(s) that Breakthrough T1D would require in order to commercialize such product, to the extent that the Research Institution has the authority to grant such rights.

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

In acknowledgement of Breakthrough T1D's provision of funding, the Research 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 to the Research 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 Research Institution from the licensing, sale, transfer or other commercial utilization of any Research Results, less payments that the Research Institution makes to any applicable inventors in accordance with the Research Institution's policies and less direct, unreimbursed out-of-pocket expenses paid by the Research Institution to third parties for patent or licensing any Research Results. The Research Institution shall make all such payments to Breakthrough T1D within ninety (90) days after the end of each calendar quarter in which such Net Income was received by the Research Institution. Upon request, the Research Institution shall provide Breakthrough T1D financial information adequate to establish and document the amount of Net Income. Breakthrough T1D shall also have the right to audit the Research Institution's books and records annually in order to verify the Net Income. The Research Institution's obligation to pay royalties to Breakthrough T1D shall survive after funding has terminated.

In the event that Breakthrough T1D has funded the patent costs of any Invention that is not assigned to Breakthrough T1D and that is later licensed, sold, or otherwise transferred by the Research Institution to a third party for commercialization, the Research Institution shall use commercially reasonable efforts to require such third party, as a condition of such license, sale or other transfer, to reimburse Breakthrough T1D for all prior funding of such patent costs.

#### **5.7.6.8 Reporting**

The Research 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 Research Institution shall promptly report to Breakthrough T1D any decision to abandon or not pursue patent protection on any Invention, With each such report, the Research 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 Policy.

In addition, the Research 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 Research 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.

Grantees are required to 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 of Breakthrough T1D grant in question. The grantee agrees to 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 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 sent to the appropriate Breakthrough T1D Scientist, Research Administrator and or Research Partnerships Staff. The Research Institution's obligation to report to Breakthrough T1D shall survive after funding has terminated.

### 5.7.6.9 Confidentiality

Breakthrough T1D shall treat as confidential all reports, invention disclosures, and other confidential information received from the Research Institution, and shall not disclose any such confidential information to any third party other than Breakthrough T1D committee members without the prior written consent of the Research Institution. Any such disclosure by Breakthrough T1D shall be made subject to appropriate confidentiality restrictions.

### 5.7.6.10 Cooperation

As reasonably requested by Breakthrough T1D, the Research 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. For example, if so requested by Breakthrough T1D, the Research 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.

In making decisions whether to continue ongoing grants or whether to award additional grants to a researcher or his/her institution, Breakthrough T1D will consider whether the institution has honored the above policy.

Grantees are required to indicate in their renewal progress reports and close-out final progress reports if any inventions were made during the funding period.

### 5.7.6.11 Conformance with Federal Law

Notwithstanding the foregoing provisions, nothing in this Policy is intended to, or should be construed to, conflict with Federal law, including any Bayh-Dole or NIH obligations that may arise with respect to Inventions resulting from research funded by both Breakthrough T1D and federal funds. Federal law shall govern in the event of any inconsistency with this Policy.

## 5.7.7 Publication Requirements

### **Deadline**

The PI can upload publications at the time of the Annual Progress Report or at any time during the grant period in [RMS360](#).

### **Authorized Personnel**

The PI is responsible for uploading the appropriate document in [RMS360](#).

### **Requirements**

Publications can be found in the 'Active Grants and Renewal' tab in the PI portal by clicking the blue button that reads 'Publications'.

## 5.7.8 Public Access Policy

### **Deadline**

It is a condition of Breakthrough T1D funding that the final peer-reviewed manuscripts be made available in the [PubMed Central](#) online archive immediately upon acceptance of journal publication.

### **Authorized Personnel**

The PI is responsible for uploading final peer-reviewed manuscripts.

### **Requirements**

- 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 should 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.

- Breakthrough T1D also strongly encourages PIs to share datasets resulting from funding in a free, publicly accessible repository, whether or not a publication resulted.
- An author must acknowledge Breakthrough T1D support in every article arising from such funding. The acknowledgement statement must include the applicable Breakthrough T1D grant number. This will enable Breakthrough T1D to link the published outputs of research to the support it has provided.

## 5.7.9 Public Announcements

### **Deadline**

Prior to any public announcement.

### **Authorized Personnel**

PI and/or RO should reach out to the contact below as well as the appropriate [Breakthrough T1D Research Administrator](#).

### **Requirements**

Please contact Breakthrough T1D Media Relations, regarding such announcements.  
(e-mail: [media@breakthroughT1D.org](mailto:media@breakthroughT1D.org) tel. 212-401-2136)

### **Affiliate Contacts**

As appropriate, please also contact the Breakthrough T1D affiliate office in the same country as the award:

**Australia:** Dorota Pawlak at [dpawlak@breakthrough1d.org.au](mailto:dpawlak@breakthrough1d.org.au)

**UK:** Rachel Connor at [rconnor@breakthrough1d.org.uk](mailto:rconnor@breakthrough1d.org.uk)

**Israel:** Efrat Tisch at [efrat@jdrf.org.il](mailto:efrat@jdrf.org.il)

**Canada:** Sarah Linklater at [slinklater@breakthrough1d.ca](mailto:slinklater@breakthrough1d.ca)

**Netherlands:** Ingrid Wiechers at [iwiechers@jdrf.nl](mailto:iwiechers@jdrf.nl)

## 5.7.10 Record Retention

See Breakthrough T1D Terms and Conditions.

## 5.7.11 Auditing

See Breakthrough T1D Terms and Conditions.

## 5.7.12 Data Sharing

For all grants awarded in FY25 or later (2025 grant keys and future), 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 in FY24 or earlier (2024 grant keys and before) are not required, but are encouraged, to make their data publicly available.

Investigators 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 may utilize Breakthrough T1D's [Figshare](#) platform via the Health Research Alliance for this purpose, at no cost (for more information [click here](#)). Please note that an [ORCID iD](#) is encouraged, but not required, to login to Figshare. If you do not log in using your ORCID account, you will need to use a gmail or other google email account to log in. We



recommend using an ORCID iD for login because it is a persistent identifier, and that account will follow you across institutions. You can register for an ORCID account and iD by following [this link](#).

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 of the Breakthrough T1D Terms and Conditions.

Exceptions to the data sharing requirement may include Postdoctoral and Advanced Postdoctoral Fellowships, Transition awards, IDDPs, and certain partnership awards, as determined by Breakthrough T1D. Selected RFAs may also be exempt, at Breakthrough T1D's discretion. Such exemption will be indicated in the RFA guidelines. Individual exceptions may be requested at the time of grant application, and subject to Breakthrough T1D's discretion.

## 5.8. Termination and Enforcement Actions

### 5.8.1 Suspension and Administrative Probation

#### **Deadline**

The Grantee Institution must respond to Breakthrough T1D within 15 days of the probation/corrective action notification.

#### **Authorized Personnel**

The Grantee Institution must designate the appropriate personnel to respond dependent on the type of probation/corrective action being taken.

#### **Requirements**

The Grantee Institution must send a rebuttal letter to the Breakthrough T1D Scientific and Administrative personnel, at which time Breakthrough T1D will make a final decision on the suitable course of action.

### 5.8.2 Terminations

#### 5.8.2.1 Breakthrough T1D-Initiated Award Termination

##### **Deadline**

Programmatic termination may be initiated by Breakthrough T1D if scientific milestones are not achieved. This determination will be made based on the required Progress Reports and/or additional programmatic information submitted to Breakthrough T1D. Breakthrough T1D will notify the Grantee Institution as soon as they have made the appropriate determination.

##### **Authorized Personnel**

Breakthrough T1D Scientific and Administrative personnel.

##### **Requirements**

Breakthrough T1D will notify the Grantee in writing of the programmatic Termination. Final Progress and Expenditure Reports will need to be submitted in [RMS360](#) no later than 60 days after the Termination date.

## 5.8.2.2 Grantee-Initiated Award Termination

### **Deadline**

Awards may also be Terminated by the Grantee, in whole or in part. The Grantee Institution must notify Breakthrough T1D as soon as they have decided that they wish to Terminate their award.

### **Authorized Personnel**

The PI must submit the Termination to the RO for final review and approval.

### **Requirements**

The Grantee Institution must notify the [Breakthrough T1D Research Administrator](#) by email with the request for Termination and the reason for this request. Upon receipt of this information, the Breakthrough T1D Research Administrator will open a 'Termination' activity in [RMS360](#) to be completed and submitted by the Grantee Institution and will notify the PI and RO of the due date for this submission. Once opened, the 'Termination' activity will be located in [RMS360](#) in the 'Active Grants and Renewal' tab in the PI portal. The PI must submit the termination to the RO for final review and approval. Final Progress and Expenditure Reports need to be submitted in [RMS360](#) no later than 60 days after the Termination date.

If a Grantee elects to Terminate a portion of their award, 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 award.

## 5.8.3 Modification of the Award

### **Deadline**

During the grant period, should Breakthrough T1D Scientific and Administrative personnel identify financial, administrative or programmatic insufficiencies, Breakthrough T1D may place special conditions on the award if corrective actions are required. Breakthrough T1D will notify the Grantee Institution as soon as there is a need to modify the award.

### **Authorized Personnel**

Breakthrough T1D Scientific and Administrative personnel.

### **Requirements**

Breakthrough T1D Scientific and Administrative personnel 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.

## 5.8.4 Recovery of Funds

### **Deadline**

Debts to Breakthrough T1D may result from recovery of funds, unobligated balances, cost disallowances, or other situations. Breakthrough T1D will notify the Grantee Institution as soon as Breakthrough T1D is aware of such debt.

### **Authorized Personnel**

Breakthrough T1D Scientific and Administrative Staff.



### **Requirements**

Breakthrough T1D Scientific and Administrative personnel will notify the Grantee Institution, in writing, of the outstanding debt owed, and will include a payment schedule and timeline for repayment for the Grantee Institution. Unpaid debts owed to Breakthrough T1D may result in administrative probation, including, but not limited to, withholding award payments for any additional or future Breakthrough T1D grant the Grantee, or the Grantee Institution may hold.

## **5.9. Grant Appeals Procedure/Rebuttal**

### **Deadline**

The Grantee Institution must respond to Breakthrough T1D within 15 days of the probation/corrective action notification.

### **Authorized Personnel**

The Grantee Institution must designate the appropriate personnel to respond dependent on the type of probation/corrective action being taken.

### **Requirements**

The Grantee Institution must send a rebuttal letter to the Breakthrough T1D Scientific and Administrative personnel, at which time Breakthrough T1D will make a final decision on the suitable course of action.

## **6. Breakthrough T1D Award Terms and Conditions**

All awards that were activated or renewed after March 1, 2014 are subject to the Breakthrough T1D Terms and Conditions that were signed off on upon Activation or Renewal of your award in [RMS360](#). Click the link to review the most recent version of [Breakthrough T1D's Terms and Conditions](#).

**Breakthrough T1D's terms are non-negotiable.** The Terms and Conditions that your institution executed can be found within each individual award in the Research Officer portal in [RMS360](#). For assistance in locating your award's Terms and Conditions, please see the [RMS360 Pre and Post Award FAQs](#) or contact your [Breakthrough T1D Research Administrator](#).

Please review the following administrative procedures in order to assist you with managing your grant in [RMS360](#) in the most effective manner.

For questions regarding any administrative procedures, please see the [RMS360 Pre and Post Award FAQs](#) or contact your [Breakthrough T1D Research Administrator](#).

## 7. Clinical Research Information

### Clinical guidelines for applicants

#### **Introduction**

The following guidelines apply to all applications regardless of award mechanism related to (1) Involving human subjects research or (2) Use of human fetal tissue must conform to Breakthrough T1D guidelines and policies, listed below. Applications that are not consistent with these guidelines will be administratively triaged without review. Breakthrough T1D funds projects that demonstrate the highest probability of completing on time and within budget, and of meeting all milestones and deliverables in conformance to these guidelines. Therefore, applicants should submit realistic budgets and research plans without the expectation of extending the project period beyond the originally approved period of performance.

#### ***Nonexempt human subjects research***

Breakthrough T1D follows the U.S. National Institutes of Health (NIH) Guidelines for the use of human subjects in research. To assure that Breakthrough T1D is supporting high quality clinical research, the grantee's institution should provide appropriate oversight and monitoring of the conduct of its clinical research portfolio, which includes observational studies that vary in size and complexity and interventional clinical trials. This guideline helps to ensure that all clinical research and clinical trials conducted under grants supported by Breakthrough T1D are well designed, conducted with rigor, and monitored adequately, and that Breakthrough T1D is kept informed of study progress through reporting. Applicants shall comply with all applicable federal, state, and local laws, regulations, and requirements.

#### **Letter of Intent (LOI) stage**

At the LOI stage please provide brief information as requested within the template to demonstrate if your proposal involves human subjects' research. If yes provide brief information on clinical study aspects.

#### **Full application stage**

All Clinical research studies are expected to adhere to the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines and applicable country specific regulatory requirements. These awards undergo a review by Breakthrough T1D Grant Review Committee with an expert clinician on the panel. Funding for these grants will not be awarded until the review process is completed. Additional ethics and/or statistical review may be done if deemed appropriate by the committee. It is strongly recommended that the principal investigator [PI] speaks with the Breakthrough T1D scientific manager prior to submitting the study documents. The following documents will be required at the full application stage.

#### ***Clinical Project Research Plan***

If your proposal includes a clinical trial [as defined by NIH clinical trial definition-please see reference section on later pages of this document], then complete all required sections of clinical project research plan template. Provide as much information as available/possible at full application. Breakthrough T1D expects the content and format of the final IRB study protocols to be in compliance with ICH GCP-E6/ country specific regulatory requirement. Applicants are allowed to

use their institute/IRB specific template, in such cases they should ensure compliance with ICH GCP-E6. For more information regarding the [clinical research toolkit, please visit NIH’s website](#). Also provide a protocol synopsis, template is referenced in the online grants management system.

**Human Subject Research Plan**

Please refer the [Applicant’s Guidelines for Clinical Classification within this document](#). Listed below are the scenarios where human subjects research plan is required. This form includes standard human subjects protection questions similar to NIH, recruitment plan and also information on other key areas that are a priority for Breakthrough T1D to improve clinical trial efficiencies as follows: It is possible every category below doesn’t apply to your project. Please provide information to the extent relevant and feasible for your project.

- Making trials more patient centric and easy to access
- Enhancing clinical trial inclusion and diversity
- Incorporating trial design efficiencies
- Leveraging technology and already available data

<b>Types</b>	<b>Needed</b>
No Human Subjects Research Proposed	Justification why the proposed studies do not constitute research involving human subjects.
Non-Exempt Human Subjects Research	HSRP and CRRP.
Human Subjects Research Claiming Exemption 1, 2, 3, 4, 5, or 6	Identify which exemption(s) (1, 2, 3, 4, 5, or 6) you are claiming and justify why the research meets the criteria for the exemption(s) that you have claimed.
Delayed-Onset Human Subjects Research	Either provide as much of the information that is requested as possible in HSRP & CRRP, OR describe why it is not possible to provide the information due to delayed-onset of human subjects research.

**Draft informed consent document**

Breakthrough T1D expects the content and format of the informed consent to be in compliance with ICH GCPE6 / country specific regulatory requirement. The guidance document is [available at this link](#). A brief checklist is also provided as an appendix to human subjects research plan template.

**Post award stage**

**Clinical milestones**

The applicant should work with their Breakthrough T1D’s scientific contact to establish appropriate project milestones to track the progress throughout the lifecycle of an award. These milestones are finalized at the time of activation.

### ***Process Prior to Subject Enrollment for Any Clinical Research***

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 that does not have the approval of the appropriate Ethics Committee (EC). All projects with human subjects 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 possible, Breakthrough T1D strongly encourages the use of a Central IRB to improve the efficiency of conducting multi-site clinical studies. The Grantee Institution must ensure that Breakthrough T1D receives required, up-to-date documentation for all sites in accordance with the Award milestone schedule and is current at the time of submission of annual award renewal materials. Failure to maintain and provide evidence of the necessary IRB certification or the equivalent would constitute a material breach of the award Terms and Conditions. The [Breakthrough T1D Administrative Resources](#) describe in detail the documentation required to satisfy the ethical approval requirement. Any changes to ethical documentation must be submitted to Breakthrough T1D 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 Breakthrough T1D. The Grantee Institution must notify Breakthrough T1D 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.

### ***Regulatory approval –e.g. Investigational New Drug or Investigational Device Exemption Requirements***

The applicant is required to follow the laws pertaining to the need of applicable regulatory authority where the research is going to be conducted which for an international trial may vary from one country to another. The awardee must provide Breakthrough T1D with any such regulatory approval documentation. For US, consistent with Federal regulations, clinical research involving the use in humans of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) under a research protocol must be performed under a Food and Drug Administration (FDA) Investigational New Drug application (IND) or Investigational Device Exemption (IDE). Exceptions must be granted in writing by the FDA. If a clinical trial funded by Breakthrough T1D will be performed under an IND or IDE or equivalent, the awardee must provide the name and institution of the IND or IDE sponsor, the date the IND or IDE was filed with FDA, the FDA IND or IDE number, copies of transmittal memos to the IND or IDE, all comments from the FDA, and the written responses to those comments. The FDA requires that the investigator wait at least 30 days from the FDA receipt of an

initial IND or IDE application for the IND/IDE to be in effect before initiating a clinical trial. The awardee must notify Breakthrough T1D if the FDA ever places the study on clinical hold and provide Breakthrough T1D any written comments from the FDA, written responses to the comments, and documentation in writing that the hold has been lifted. The awardee may not use award funds to enroll new subjects in a clinical study during a clinical hold.

### ***Clinical trial registration***

Breakthrough T1D requires all applicable clinical trials [including all non-exempt human subjects research] be registered in a clinical trial registry [country specific or international] e.g.

Clinicaltrials.gov database to ensure information is freely available on Breakthrough T1D funded trials within the T1D community. The registration should be no later than 21 days after the first subject is enrolled.

### ***Study Status/Progress Reports and Documentation***

In order to stay apprised of Breakthrough T1D supported clinical study activities and progress, Breakthrough T1D scientific program manager will work with the PI requesting specific information in the quarterly and/or annual progress report in addition to the information requested in Breakthrough T1D's online grants management system or the progress report template [e.g. recruitment, milestone, clinical trial population diversity metrics, renewal, etc.]. Standard templates for such will be available in Breakthrough T1D's online grants management system.

### ***Required Time-Sensitive Notifications for Clinical Trials***

Clinical trials funded by Breakthrough T1D must follow ICH GCP/applicable regulatory requirement related to guidelines for safety reporting and reporting of unanticipated problems. Breakthrough T1D scientific program manager should be informed within 24 hours of notifying the Serious Adverse Event (SAE) to IRB and/or regulatory as applicable.

### ***Clinical trial-Final progress reporting, If applicable***

For all clinical trials, at final progress reporting, Breakthrough T1D requires applicants to fill out a clinical trial results synopsis. Reference template is available in the online grants management system. This document will be completed by the applicant and uploaded as a separate attachment at final progress reporting in the online system.

## **References**

- Breakthrough T1D scientific guidelines-version 2011, 2015
- Templates referenced in online grants management system
- Pre-award
  - Clinical trial Letter of intent template
  - Clinical Research Plan
  - Protocol Synopsis
  - Human Subject Research Plan
- Post-award
  - Final progress report-clinical trial section
- NIH's Definition of a Clinical Trial -<https://grants.nih.gov/policy/clinical-trials/definition.htm>
- Definitions

- Clinical Research: is research with human subjects that is: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research. Note: Studies falling under Exemption 4 for human subjects' research are not considered clinical research by this definition.
- Human Subjects: The DHHS regulations "Protection of Human Subjects" (45 CFR 46, administered by OHRP) define a human subject as a living individual about whom an investigator conducting research obtains:
  - data through intervention or interaction with the individual or
  - identifiable private information.
- Investigator: The OHRP considers the term investigator to include anyone involved in conducting the research. OHRP does not consider the act of solely providing coded private information or specimens (for example, by a tissue repository) to constitute involvement in the conduct of the research. However, if the individuals who provide coded information or specimens also collaborate on other activities related to the conduct of the research with the investigators who receive such information or specimens, they will be considered to be involved in the conduct of the research. (See OHRP's Guidance on Research Involving Coded Private Information or Biological Specimens: <http://www.hhs.gov/ohrp/policy/cdebiol.html>.)
- Research: DHHS regulations define research at 45 CFR 46.102(d) as follows: Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.
- Obtains: In general, obtaining identifiable private information or identifiable specimens includes, but is not limited to: (a) observing or recording private behavior; (b) using, studying, or analyzing for research purposes identifiable private information or identifiable specimens provided to investigators from any source; and (c) using, studying, or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the investigators.
- Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. (45 CFR 46.102(f))
- Interaction includes communication or interpersonal contact between investigator and subject. (45 CFR 46.102(f))

- Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) for obtaining the information to constitute research involving human subjects. (45 CFR 46.102(f))
- Individually Identifiable Private Information According to its guidance for use of coded specimens, OHRP generally considers private information or specimens to be individually identifiable as defined at 45 CFR 46.102(f) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems. Conversely, OHRP considers private information or specimens not to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

## Clinical classification guidelines for applicants

### Scenario A. No Human Subjects Research

If no human subjects research is proposed in the application, select the appropriate option. No HSRP and CRRP required for this category.

If proposed studies using human data or biological specimens do not involve human subjects, provide an explanation of why the proposed studies do not constitute research involving human subjects.

The explanation could include: a description of the source of the data/biospecimens and whether there is any intervention or interaction with the subjects in order to obtain the specimens and data; what identifiers will be associated with the human specimens and data and who has access to subject identities; the role(s) of providers of the data/biological specimens in the proposed research; and the manner by which the privacy of research participants and confidentiality of data will be protected.

Research that does not involve intervention or interaction with living individuals, or identifiable private information, is not human subjects research. Research involving the use of coded private information or biological specimens may not constitute human subjects research if the conditions of the [OHRP Guidance on Research Involving Coded Private Information or Biological Specimens](#) have been met.

Research that only proposes the use of cadaver specimens is not human subjects research because human subjects are defined as “living individuals.” The use of cadaver specimens is not regulated by 45 CFR part 46, but may be governed by other Federal, State or local laws.

### Scenario B. Non-Exempt Human Subjects Research

If research involving human subjects is anticipated to take place under the award, select the appropriate option. In the HSRP and CRRP, you must provide sufficient information for reviewers to determine that the proposed research meets the requirements of the DHHS regulations to protect



human subjects from research risks (45 CFR part 46). Follow the instructions in the HSRP and CRRP to provide the required information.

### Scenario C. Exempt Human Subjects Research

If all of the proposed human subjects research meets the criteria for one or more of the exemptions from the requirements in the DHHS regulations (46.101(b)), select the appropriate option and NA entered for the Human Subject Assurance Number since no OHRP assurance number is required for exempt research.

Please visit [HHS's website](#) to decide if the research falls into one of the exempt categories. Following are the six categories:

**Exemption 1**, as it pertains to research involving human subjects defined in 46.101(b) – in order for proposed research to be exempt from the requirement for continuing IRB review and approval, investigators must propose research in educational settings involving normal educational practices, such as:

- (i) Research on regular and special education instructional strategies, or
- (ii) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

**Exemption 2**, as it pertains to research involving human subjects defined in 46.101(b) – in order for proposed research to be exempt from the requirement of continuing IRB review and approval under exemption 2, researchers must propose the use of educational tests, survey or interview procedures, or observations of public behavior involving human subjects who:

cannot be identified, either directly or indirectly; OR may be identified, but would not be put at risk if information is disclosed

**Exemption 3**, as it pertains to research involving human subjects defined in 46.101(b) – in order for proposed research to be exempt from the requirement of continuing IRB review and approval, investigators must propose the use of educational tests, survey or interview procedures, or observations of public behavior that does not meet the requirements for Exemption 2 if: the human subjects are elected or appointed public officials; or the human subjects are candidates for public office; or

Federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained during and after the proposed research

**Exemption 4**, as it pertains to research involving human subjects defined in 46.101(b) – in order for proposed research to be exempt from the requirement of continuing IRB review and approval under Exemption 4, investigators must propose the use of data or samples that are either:

existing and publicly available; OR existing and unidentifiable to the research team

**Exemption 5**, as it pertains to research involving human subjects defined in 46.101(b) – in order for proposed research to be exempt from the requirement of continuing IRB review and approval under Exemption 5, investigators must propose research and demonstration projects conducted by or



subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

public benefit or service programs;

procedures for obtaining benefits or services under those programs;

possible changes in or alternatives to those programs or procedures;

OR

possible changes in the methods or levels of payment for benefits or services under those programs

**Exemption 6**, as it pertains to research involving human subjects

defined in 46.101(b) – in order for proposed research to be exempt from the requirement of continuing IRB review and approval under Exemption 6, investigators must propose research involving taste and food quality evaluation and consumer acceptance studies if:

wholesome foods without additives are consumed;

a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture; or

a food is consumed that contains an agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture

Provide a justification for the exemption(s) containing sufficient information about the involvement of human subjects.

When in doubt, consult with the Office for Human Research Protections (OHRP), Department of Health and Human Services by accessing their [website](#) for guidance and further information.

Please note: if the proposed research involves only the use of human data or biological specimens, you should first determine whether the research involves human subjects. The exemptions do not apply if the research does not involve human subjects. For help determining whether research that involves the use of human data or biological specimens is human subjects research, please refer to [this website](#).

#### **Scenario D. Delayed-Onset Human Subjects Research**

If human subjects research is anticipated within the period of the award but plans for involvement of human subjects cannot be described in the application as allowed by the DHHS regulations (45 CFR part 46.118), select the appropriate option. In the section on Protection of Human Subjects in the Research Plan, you should either include an explanation of anticipated protections for human subjects or an explanation of why protections cannot be described.

Examples of delayed-onset of human subjects research include:

- Human subjects research is dependent upon the completion of animal or other studies; or
- Human subjects research protocols to be included will undergo an independent decision-making process (often defined by a FO).

In rare situations, applications are submitted with the knowledge that human subjects will be involved during the period of support, but plans are so indefinite that it is not possible to describe the involvement of human subjects in the application. The kinds of activities that lack definite plans are often institutional awards where the selection of specific projects is the institution's responsibility, research training grants, and projects in which the involvement of human subjects depends upon completion of instruments, animal studies, or purification of compounds.

If the involvement of human subjects cannot be fully described, in HSRP provide a detailed explanation why it is not possible to develop definite plans at this time. If the involvement of human subjects depends upon information that is not presently available (e.g., completion of instruments, animal studies, purification of compounds), be explicit about the information and the factors affecting the availability of the information. Describe the information that will be necessary in order to develop definite plans for the involvement of human subjects, why that information is not currently available, and when the information is expected to become available during the course of the project.

If an award is made, prior to the involvement of human subjects the grantee must submit for prior approval either (1) detailed information as required in the Research Plan, Protection of Human Subjects (addressing risks to the subjects, adequacy of protection against risks, potential benefits of the proposed research, importance of the knowledge to be gained, and data and safety monitoring plan if applicable) and certification of IRB approval, OR (2) if all of the research meets the criteria for one or more exemptions, identification of which exemption(s) is/are applicable to the research, and a justification for the exemption with sufficient information about the involvement of human subjects to allow a determination that the claimed exemption is appropriate.

Under no circumstance may human subjects be involved in research until approval is granted by the awarding entity, and certification of IRB approval has been accepted by the agency.

Follow the instructions that are identified for each of the topics in the HSRP and CRRP and EITHER provide as much of the information that is requested as possible, OR describe why it is not possible to provide the information due to delayed-onset of human subjects research.

## 8. T1D Outcomes Program

Background Decisions about medical products for people with type 1 diabetes (T1D) currently focus primarily on HbA1c to assess glycemic control and as a surrogate for the risk of developing complications. Advances in T1D technology have made it feasible to assess the efficacy of therapies and technologies using a set of outcomes beyond HbA1c that better reflect day-to-day glycemic control and how a patient feels, functions and survives. However, the outcomes beyond HbA1c have not been standardized or defined consistently.

To address this issue, the T1D-stakeholder community launched the Type 1 Diabetes Outcomes Program to develop consensus definitions for a set of priority outcomes for T1D, namely hypoglycemia, time in range, hyperglycemia, diabetic ketoacidosis (DKA), and patient reported outcomes (PROs). A Steering Committee – comprised of representatives from the American Association of Clinical Endocrinologists, the American Association of Diabetes Educators, the American Diabetes Association, the Endocrine Society, Breakthrough T1D, The Leona M. and Harry B. Helmsley Charitable Trust, the Pediatric Endocrine Society, and the T1D Exchange – was the decision-making body for the T1D Outcomes Program. The work of the Steering Committee was informed by input from diabetes researchers, industry, and people with diabetes through Advisory Committees representing each stakeholder group.

Consensus Reached The Steering Committee, informed by published evidence, their clinical expertise and input from researchers, industry, and people with diabetes, developed definitions for hypoglycemia, hyperglycemia, time in range, and diabetic ketoacidosis in T1D. The definitions developed, presented in the table below, reflect the Steering Committee’s assessment of the outcome’s short- and long-term clinical impact on people with type 1 diabetes. The consensus was formally endorsed by the leading diabetes clinician organizations, including the American Diabetes Association (ADA) and published in Diabetes Care<sup>1</sup>. A press release announced the release of the publication. For PROs, the Steering Committee determined that further work is needed to develop standard PROs for T1D.

<sup>1</sup> Diabetes Care 2017 Dec; 40(12): 1622-1630. <http://care.diabetesjournals.org/content/40/12/1622>

Outcome	Definition
<b>Hypoglycemia</b>	<ul style="list-style-type: none"> <li>• Level 1: Glucose &lt; 70 mg/dL (3.9 mmol/L) and Glucose ≥ 54 mg/dL (3.0 mmol/L)</li> <li>• Level 2: Glucose &lt; 54 mg/dL (3.0 mmol/L)</li> <li>• Level 3: A severe event characterized by altered mental and/or physical status requiring assistance</li> </ul>
<b>Hyperglycemia</b>	<ul style="list-style-type: none"> <li>• Level 1 – Elevated Glucose: Glucose &gt; 180 mg/dL (10 mmol/L) and Glucose ≤ 250 mg/dL (13.9 mmol/L)</li> <li>• Level 2 – Very Elevated Glucose: Glucose &gt; 250 mg/dL (13.9 mmol/L)</li> </ul>
<b>Time in Range</b>	<ul style="list-style-type: none"> <li>• Percentage of readings in the range of 70 mg/dL – 180 mg/dL (3.9-10.0 mmol/L) per unit of time</li> </ul>
<b>Diabetic Ketoacidosis</b>	<ul style="list-style-type: none"> <li>• Elevated serum or urine ketones (greater than the upper limit of the normal range), and</li> <li>• Serum bicarbonate &lt; 15 mmol/L or Blood pH &lt; 7.3</li> </ul>

**What is Needed?** Now that consensus has been reached on definitions for the outcomes beyond HbA1c, it is important for these outcomes to be consistently utilized in clinical trials so that they become standard in the T1D community. To that end, Breakthrough T1D requires that all newly Breakthrough T1D-funded clinical studies incorporate the outcomes above that are appropriate for



that study. Further, for those outcomes incorporated into a study, they should be consistent with the definitions from the publication (also included in the table above) and we recommend their usage as endpoints in all T1D studies. For any deviations from these definitions, a justification should be provided for our consideration.

## 9. Contact us

### **Research Administration & Operations**

For information regarding submission of applications and other pre-award related inquiries please contact [preawardsupport@BreakthroughT1D.org](mailto:preawardsupport@BreakthroughT1D.org)

For information regarding active awards and other post-award related inquiries please contact [postawardsupport@BreakthroughT1D.org](mailto:postawardsupport@BreakthroughT1D.org).

### **Media**

To coordinate Press Releases, please contact our Media inbox at [media@BreakthroughT1D.org](mailto:media@BreakthroughT1D.org).

### **Please mail all documentation/requests to:**

Breakthrough T1D Media Department  
200 Vesey Street, 28th Floor  
New York, NY 10281  
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