Boston Children's Hospital
Until every child is well™

Technology & Innovation Development Office

Therapeutic & Medical Device Accelerator Internal Funds

Policies and Guidelines

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Overview and Objectives

The mission of Boston Children's Hospital's (BCH's) new Therapeutic and Medical Device Accelerator ("the Accelerator") at the Technology & Innovation Development Office ("TIDO") is to transform innovative projects from BCH into therapeutic and medical device solutions to significantly improve patient care.

The Accelerator supports BCH faculty in the development of translational research towards commercialization in line with BCH's core values through cash and in-kind contributions by the Accelerator. We de-risk selected projects to either facilitate partnerships with industry or create new companies.

The Accelerator's Internal Funds consist of a combination of two former internal funding sources: the Technology Development Fund (TDF) and Drugs, Devices and Diagnostic Accelerator (D3A) award. The Internal Funds support early-stage academic BCH projects to bring them to their next value inflection point. In addition to funding, the Accelerator team members provide industry-level support (milestone-based project management, drug discovery and development expertise, intellectual property, business development) to the selected research teams to help drive the value of their projects.

The Accelerator Internal Funding initiative has the following objectives:

- **Unite similarly existing programs** (TDF and D3A) into one comprehensive new funding and supporting structure that will accelerate the development of high value discovery programs;
- **Enhance translation of science** into novel and innovative new therapies, devices and diagnostics that meet a significant unmet medical need for children while doing so in a capital and time efficient manner;
- **Improve commercialization** and expedited clinical development awareness and skill among faculty; and
- **Increase value** of BCH scientific discoveries and expedite the translation of these into our clinical mission and/or increase return on funding into research for all BCH stakeholders.

Program Eligibility

Applicant

Any principal investigator (PI), whose employer is BCH and who has an obligation to assign their Intellectual Property (IP) rights BCH, is eligible to apply.

Project eligibility

The Accelerator Funds are intended to fund work that supports the advancement of technology, IP, and technical validation, either for Therapeutic or for Medical Device/Diagnostic projects. The foundational IP should be owned or co-owned by BCH (with BCH as lead commercialization agent) and not optioned, licensed, or otherwise committed to a commercial entity (via MTA or other agreement).

Therapeutics

Eligible projects can be related to the development of either small molecules or biotherapies (antibodies, oncolytic viruses, gene and cellular therapy approaches, synthetic peptides, ribonucleic acid (RNA)-based approaches, etc.).

The Accelerator Funds are to be used to develop projects starting at least at the Target Validation stage in the drug/biologics discovery and development chain. Typical activities to be funded by this program but not limited thereto are:

- Target Validation (Confirmation activities) (adapted from Sygnature Discovery website - Source: https://www.sygnaturediscovery.com/drug-discovery/integrated-drug-discovery/target-validation)
    - *In vitro* assays to measure the biological activity of the target, characterize pharmacology and assess the effects of modulating function
    - Use of "tool" molecules to demonstrate desired *in vitro* biological effects
    - Correlation of expression with disease progression or exacerbation using disease-relevant cells/tissue
- Hit Identification:
    - Virtual Screening (in silico structure-based drug design);
    - High Throughput Screening;
    - Fragment Screening
- Hit to lead /Lead optimization:
    - Design of new analogs based on hit compounds series;
    - Structure-activity relationship analysis;
    - Optimization of selective small molecule modulators of novel therapeutic targets
- Preclinical studies:
    - Preclinical development of validated lead molecules or biologics or novel modalities (e.g., ADME/T, PK/PD, formulation, or safety studies)
    - *In vivo* evaluation of drug candidates, such as identification of minimum effective dose, therapeutic window;
    - Testing of lead molecules or biologics in cell-based and/or animal models of disease to confirm their clinical or diagnostic relevance;
    - Preliminary non-GLP safety studies;
    - Initial formulation and production of preclinical material

Medical Devices/Diagnostics

We will typically fund projects that start at Technology Readiness Levels (TRL) 3 to 6. Definition of the TRL levels can be found here (Source: Biomedical DoD Technology Readiness Levels (TRLs): Medical Devices | Tier Seven (tier7.us)). Types of projects to be supported by Accelerator Funds but not limited thereto are development and validation of:

- Clinical biomarkers and/or relevant diagnostic methods;
- Drug delivery technologies;
- Diagnostic antibodies or other diagnostic biologics;
- Surgical devices.

Eligible Costs

Most of each project's budget should be geared towards activities to be outsourced to core facilities (relevant academic or private setting in the US, in Canada or other eligible location), Clinical Research

Organizations (CROs), Contract Development & Manufacturing Organizations (CDMOs), expert consultants and reagents/materials specifically related to the funded project. Potential activities undertaken in the PI's laboratory should aim at transferring knowledge or material to those facilities/organizations.

Non-eligible Costs

The Accelerator Funds cannot be applied towards:

- Purchase of equipment
- Purchase of computers
- Travel/conferences expenses
- Principal Investigator salary support or salary of collaborators at other institutions
- Same research activities expenses already supported by other funding mechanisms.

Number of Applications

An Investigator:

- May only submit one (1) project to a funding cycle as a Principal Investigator; or
- May participate in a maximum of two (2) projects as a Co-investigator (i.e. investigator other than the Principal Investigator, affiliated to BCH).

Award Types and Funding Levels

Accelerator Funds are directed towards either Therapeutic or Medical Devices/Diagnostics projects. Co-funding from other partners (foundations, government programs, others) is not mandatory but encouraged.

Therapeutic Awards

Therapeutic projects will be managed according to the project plan and funded in line with the activities required to complete predefined milestones, including Go/No Go decision points.

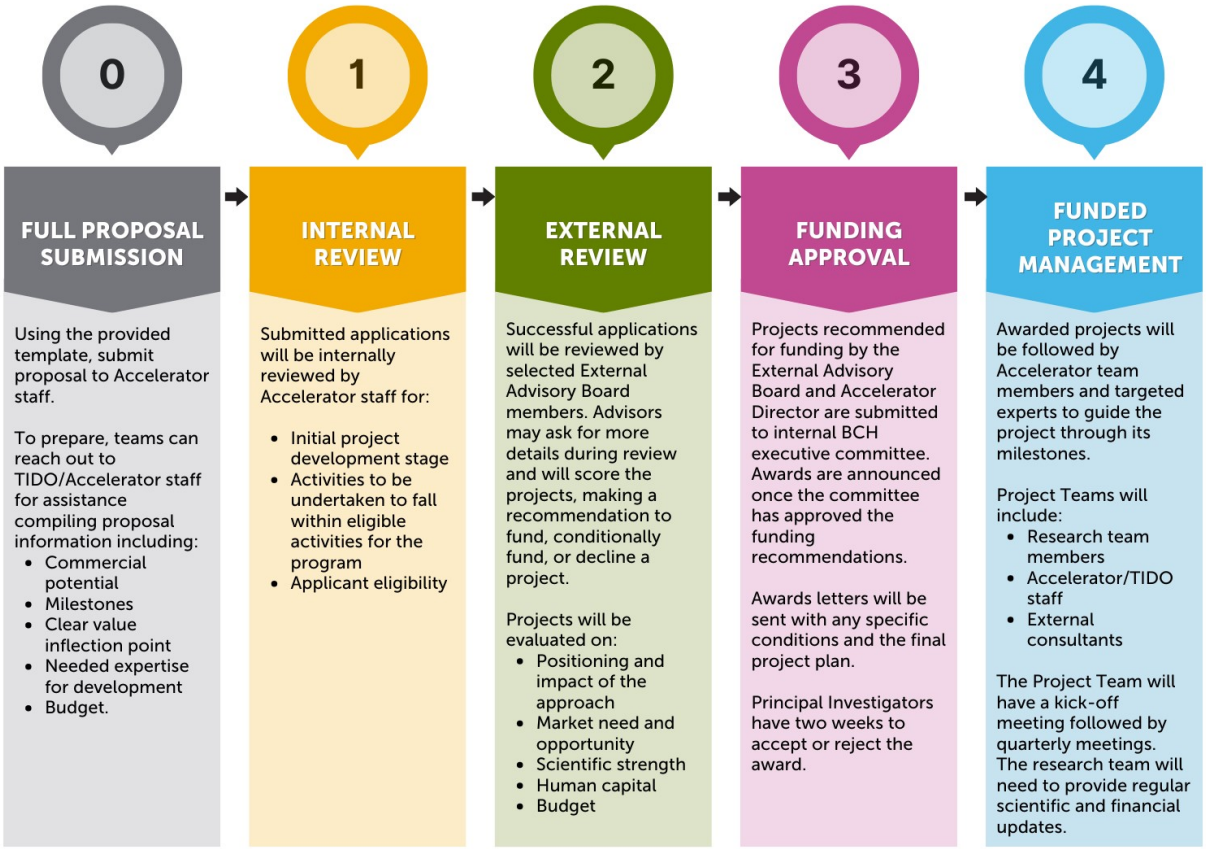
- Target validation activities: up to $150,000 for up to 12 months
- Hit identification activities: up to $300,000 for up to 18 months
- Hit to lead activities: up to $500,000 for up to 18 months
- Lead optimization and + activities: up to $1,000,000 for up to 24 months

Medical Devices/Diagnostic Awards

Medical Device/Diagnostic projects will be funded at a maximum of $150,000 per project for a period of up to 18 months.

Review, Selection & Management Process

The Process is schematized below, followed by further details about each step.



Pre-submission – Stage 0

All applicants must submit a full proposal based on templates provided here.

In the preparation phase of their application, research teams can reach out to Accelerator staff and/or other relevant TIDO staff members (licensing managers, BD experts) to help with their proposals to include: additional information on the project's commercial potential, relevant milestones toward reaching a clear value inflection point, appropriate expertise for development of the project (Core facilities, CDMO/CRO services) and related budget.

Internal Review – Stage 1

Once applications are submitted, they will be internally reviewed by Accelerator staff for:

- Initial stage of development of the project
- Activities to be undertaken to fall within eligible activities for the Program
- Eligibility of applicant

External Expert Reviews – Stage 2

Applications that have successfully gone through the Internal Review will be evaluated by selected External Board members. Each Application will be reviewed by three (3) members of the External Advisory

Board, selected according to their area of expertise as relevant to each project. All External Advisory Board members are operating under complete confidentiality, in compliance with BCH's policies. The Advisory Board may ask for further details during their review. The Advisors will review and score the projects based on evaluation criteria (see below for details) and make one of the following recommendations:

- Approval for funding;
- Conditional approval for funding (specific aims must be modified);
- Funding request declined.

Evaluation Criteria

Proposals will be evaluated on scientific excellence and commercialization potential, in line with BCH's mission. More specifically, evaluation will be focused on:

- Positioning and Impact of the approach:
  - Relevance of the problem for a defined initial patient population;
  - Context, reliability of preliminary results;
  - Innovation of the approach;
  - Clear definition of scientific objectives;
- Significant market need and opportunity:
  - Clear unmet medical need;
  - Business opportunity/market size;
  - Competitive positioning over existing approaches;
  - High potential interest from industry partners;
- Strength of scientific proposal:
  - Feasibility of the research plan, including clear milestones and go-no go decision points;
  - Identification and relevance of key services to be involved (core facilities, targeted CDMOs/CROs);
  - Clear deliverables;
  - Identification of potential risks and mitigation plan;
  - Potential of generating high-value IP assets;
- Human Capital:
  - Strength of the research team;
  - Relevant diversity of team members;
- Budget:
  - Realistic budget aligned with proposed project activities;
  - Clear demonstration of the need for the funds to reach a next value-inflection point.

Funding Approval – Stage 3

The projects recommended for funding by the Accelerator External Advisory Board by the Accelerator Director are submitted to an internal BCH executive committee (the BCH Internal Fund Parent Committee) for final funding approval. Awards are announced once the Parent Committee has approved the Accelerator's funding recommendations.

The award letter sent to the Principal Investigator will communicate any specific conditions of the award as well as the final project plan, as approved/adjusted considering the Committee's recommendations.

The Principal Investigator will have two (2) weeks to accept or reject the award.

Funded Project Management – Stage 4

Each awarded project will be followed by dedicated Accelerator team members and targeted experts to guide the project through its milestone-based progress.

Each Accelerator Project Team will include:

- Research team members: PI and research personnel;
- Accelerator/TIDO staff: administrative and scientific project managers, licensing manager in charge of the portfolio, BD/strategic alliances personnel;
- External consultants, when needed, with specific technical expertise (e.g., for therapeutics: medicinal chemistry, PK/PD, regulatory; for medical devices: regulatory, others).

The Accelerator Project team will have an initial kick-off meeting followed by quarterly meetings during which the research team members will provide scientific updates on the project.

Regular (frequency to be determined at start of project) scientific and financial reports will be required from the Research team. Templates for the required documents will be provided to the Applicant.

Publicity

The Applicant is expected to acknowledge Accelerator funding in public presentations and publications when financial support is referenced.

Please contact TIDOAccelerator@childrens.harvard.edu with any questions.

Appendix 1

Conditions of Accepting Accelerator Funding

By accepting Accelerator funds the PI agrees to:

- Use the funds as specifically described, and for the specific aims, detailed in the project plan. The project plan cannot be changed without Accelerator Director approval;
- Inform the Accelerator Director if the PI, or the BCH employee performing the work and leading the project, intends to leave BCH;
- Inform the Accelerator Director if the PI is awarded an internal or external grant that supports any of the same specific aims as those proposed in the approved project plan;
- Generate all the agreed upon deliverables detailed in the project plan upon end of the project and return any undisbursed funds; and
- Acknowledge and accept that any revenue received by BCH regarding any IP created, invented, further developed, or otherwise supported by, or with funding from the Accelerator Funds will be distributed in accordance with the revenue sharing table below.

Stakeholder	BCH Standard Distribution	Tx MD Acc Funding (SCIEBIC/D3A/TDF)
Institution / Research Endowment	30%	30%
Inventor(s)	30%	**21.25%**
Department	12.5%	**6.25%**
Laboratory	12.5%	**6.25%**
Tech Transfer Office/Other	15%	15%
Funding Source		**21.25% until 1.2X returned**

Projects which have not been completed within the agreed upon project duration from the award date will expire unless the awardee requests a no-cost extension (to be granted at the Accelerator Director's discretion). A request for extension must include the reason for the delay, evidence that the project remains relevant and timely, and a plan for completing the project within the next 12 months. No-cost extension requests will be considered/evaluated by the Accelerator Director.

The Accelerator reserves the right to put funding on hold or terminate funding and request for reimbursement of any unspent funds, should any of the following occur:

- A project is optioned or licensed to a company during the award period;
- Completion of the project goes beyond the agreed upon term in the finalized project plan without a no-cost extension;
- The focus of the project deviates from the proposal approved by the Advisory Board without consultation with the Accelerator Director;
- The laboratory no longer has the staffing needed to complete the project;
- The milestones are met before the full grant award is spent.

Appendix 2

IP and Revenue Sharing Principles

There is no requirement to have IP filed prior to applying; however, any background IP relevant for the project should be available. Any new inventions that are conceived or reduced to practice while performing an Accelerator-supported research project must be disclosed to TIDO and, thereafter, assigned exclusively to BCH. The PI ***must*** report all inventions to TIDO no fewer than 30 days in advance of a public disclosure to allow TIDO staff to determine if such public disclosure contains new, potentially patentable subject matter.

IP conceived, reduced to practice, or otherwise made, improved, or further developed with Accelerator support and assigned to BCH will be managed in accordance with BCH's IP Policy, whether or not such IP includes a co-inventor(s) from a non-BCH institution.

Terms of potential revenue sharing between BCH and other institutions will be negotiated on a case-by-case basis according to the projects funded.