JOHNS HOPKINS TECHNOLOGY VENTURES

FASTFORWARD

JHTV TRANSLATIONAL FUNDING APPLICATION GUIDE

Johns Hopkins University Grant Programs consist of three philanthropic programs created specifically for Hopkins innovators whose work has progressed beyond the basic research phase and are developing innovations and discoveries for specific **commercial applications**. The awards are intended to provide seed funding for vital proof-of-concept and validation studies that clearly confirm endpoints that indicate derisking of a specific commercial opportunity. Examples of work that is appropriate for this funding include in-vivo testing, prototype design & fabrication, pre-clinical testing, verification testing, market research, and regulatory & reimbursement consulting. Many applicants find it helpful to participate in one of the I-Corps short course sessions offered by JHTV as this enables applicants to better identify their customers, develop value propositions, and realistically estimate the size of their commercial opportunities.

This guide is provided to assist applicants in understanding the application sections and how they are scored and evaluated. Key attributes of successful submissions include:

- Proposed research that relates directly to a specific identified market need
- Intellectual property that is clearly described and defensible
- Objectives that are quantifiable, market relevant, indicative of commercial potential, and viable within the nine-month award time period and within the associated budget
- A clearly stated business case, including path to market and end user adoption mechanisms
- Clear demonstration of the development path of the technology and how the award will fund work that leads to the next important milestone

All applications are reviewed by a committee comprised of relevant industry members as well as faculty and staff. Evaluation of proposals is on the basis of innovation and scientific merit, prospective market impact, technical feasibility, and commercialization potential. Each section of the application is scored along the following criteria:

SCORE	CRITERION
5 – Excellent	The applicant has included **all** of the required information and has made a **very convincing** argument in support of the criterion being scored.
4 – Above Average	The applicant has included **all** of the required information and has made a **reasonable** argument in support of the criterion being scored.
3 – Good	The applicant has included **most** of the required information and has made a **fair** argument in support of the criterion being scored.
2 – Fair	The applicant has provided **most** of the required information but has **not made a fair** argument in support of the criterion being scored.
1 – Poor	The applicant has **not** provided enough of the required information to make a fair argument in support of the criterion being scored.

Below are points to consider in completing each section of the application. As a general rule, simple and direct responses are best. Graphics, charts, and tables are often useful and should be directly referenced. Successful applications demonstrate in a concise manner how the funds have a meaningful impact on commercialization advancement of their technology. As a reminder, your font size should be a minimum of ten, and your margins a minimum of 0.5 inches. **This application must not exceed 5 pages, excluding the cover page and letters of support.**

1. TECHNOLOGY DESCRIPTION, STATUS, AND INTELLECTUAL PROPERTY

- The description should focus on how the Technology is unique/novel in its approach to solve an important commercial problem relative to other approaches in the scientific literature and/or other commercial products. Is the project accurately and well described? How is the project unique or a significant advancement? Does the project solve a large problem or unmet need?
- Describe the status of the Technology's development including the studies completed, data generated, and the conclusions derived for an audience of business professionals who have a high level of understanding in the field.
- Any preliminary data or other results suggesting that the Technology is likely to work as predicted should be included. Is the data meaningful or indicative of potential success? Why?
- Describe the intellectual property secured for the Technology and strategies for strengthening the Technology's intellectual property portfolio. In what way(s) is the Intellectual property strong (if filed) or likely protectable when filed?

2. APPLICATION OF TECHNOLOGY AS A PRODUCT AND COMMERCIAL MARKET ASSESSMENT

- The purpose of this requirement is to demonstrate that you have thought through how your work translates to a specific customer and application and to have a basic but realistic assessment of your commercial market opportunity. A sophisticated market analysis is not required.
- Describe potential commercial products or services that could be based on the technology. Is the commercial opportunity large or impactful?
- Describe how these products will solve a problem in the market and the overall importance of solving that problem.
- Include a description of the customer who will buy the product or service and a brief summary of the size of the market opportunity that these customers represent. Is there a clearly identified application and customer? Market opportunities identified should be realistic in terms of the likely number of potential users and the price that will be paid for the specific product or service.
- Include a description of the value proposition (ideally quantified) that these products will bring to customers – specific customer problem solved or need satisfied such as cost savings, time savings, convenience, improved outcomes, etc. Is the value proposition compelling? To whom? Why?
- Outline a general description of the technology's competitive advantages over competing products and services. If possible, include a table, picture or other graphic that compares key features of your product with competing products that are either on the market or in development. Are these advantages significant? Ordered by importance to the customer?

3. COMMERCIALIZATION PATHWAY AND RISK ASSESSMENT

- This purpose of this section is to describe the major milestones needed to move your technology from its current state to a commercial product. This includes milestones beyond the nine-month funding period covered by the grant. In the next section you will provide detail on the milestones covered in the nine months of the grant and their significance to the commercialization path.
- Provide an overview of the overall steps/milestones needed to commercialize the Technology (beyond the funding) including how long it will take and how much it will cost to achieve key milestones. Does the section describe the major steps and milestones needed to bring the product to where it will be commercially sold? Are the steps and milestones well-defined, appropriate, and realistic? Include significant intellectual property and regulatory milestones.
- Describe how you see the technology being licensed, such as via startup company or a license to a corporate entity. In either case, identify potential commercial partners and the level of interest those partners have in the technology, if any.
- The major risks of failure (beyond the proposed project, e.g., technology risk, market risk, etc.) should also be described along with the applicant's plans to manage and mitigate those risks.

4. PROJECT DESCRIPTION, MILESTONES, AND DETAILED BUDGET/JUSTIFICATION

- The purpose of this section is to provide detail on the milestones covered in the nine months of the grant and their significance to the commercialization path described in the Section 3 above. Proposed costs should be directly tied to project advancement.
- Include a summary of the proposed project and the anticipated milestones and a clear timeline. The project timeline should not exceed nine months. Are the steps and milestones well-defined, appropriate, and realistic within nine months? Are they the correct ones to objectively/quantitatively demonstrate success in achieving the milestones over the nine-month timeframe?
- Describe how each of the milestones leads to a clear demonstration or validation of the technology for the proposed commercial purpose and how it advances the technology along the commercialization pathway. Milestones must be quantifiable and measurable so it will be obvious when they have been successfully or unsuccessfully met. Does reaching each milestone clearly demonstrate how it positions the technology development to move to the next significant milestone? Charts or graphs showing how the proposed scope of work and funding fits in the commercialization sequence described in Section 3 are often useful.
- A budget of the costs required to conduct the project should be provided. Is the proposed budget accurate and realistic for the time frame? Quantifying the amount of the proposed award to be used in each milestone of the proposed scope of work is helpful.
- A justification of the significant project costs (typically over $5,000) should be provided.
- Please note that if the research plan is slated to be conducted during the regular academic year, you may not include faculty salary support. JHU Translational Funding Awards are made directly to the faculty recipients. Indirect costs are not covered and should not be included in the proposed budget.

5. LETTER OF SUPPORTMENT

- Letters of support are helpful but not required. Reviewers understand that external disclosures may be limited or nonexistent in order to protect intellectual property.
- Impactful letters of support validate provide external validation of key components the application.
- Useful letters of support:
    - Confirm the technology as impactful and leading edge
    - Validate a commercial market need
    - Indicate a willingness to assist, use, license or fund
    - Often reflect past interaction
    - Indicate an increased likelihood of commercial success as a result of the milestones funded
- Letters from potential vendors or suppliers are not helpful as they do nothing to validate key components of the application.
- Letters of support are not required to fit in the five page limit of the application

SAMPLE EXHIBITS

The exhibits below are for illustrative purposes only. Applicants should feel free to use other formats such as pictures and graphs. The key is to create exhibits that clearly and concisely convey information. Multiple examples are given, but only one is needed per section.

COMMERCIAL MARKET ASSESSMENT

Our target market includes over 5,000 neurosurgical centers in the U.S. and 3,600 neurosurgeons. The incidence of XYZ is 1.1-20.5 per 100,000 people per year, or around 5,000-65,000 people per year in the US (US Census Bureau, 2018). We are targeting 20% of patients who require surgical intervention, and 5-25% of cases that require repeat surgery. Assuming that each center makes a capital purchase at $175,000, we estimate a target addressable market of $950M, with another $170M per year for disposable kits ($10,000 per case, assuming an average of 17,000 surgical cases per year) and $225M for annual maintenance and upgrades ($40,000 per device). If we focus on the 1,236 hospitals that treated at least 250 Medicare inpatients in 2014-2016 (US News & World Report, 2019), we estimate the serviceable addressable market for the capital purchase to be $216M. We hypothesize that customers would be willing to pay this price, as they are already purchasing other neurosurgical equipment at significantly higher costs, e.g. ABC's XYZ ($280,000 per device, $22,000 per disposable kit). We will continue our customer discovery to test this hypothesis and ensure that our device can fit into the customers' workflow and business models. If we gain early traction for our device, we anticipate that the demand will increase as the geriatric population continues to expand worldwide.

Competitive Analysis

	Product A	Product B	Product C		Our Prototype
Cost/test	$100.00	$75.00	$120.00		$50.00
Time/test (min)	75	120	60		30
Sensitivity	89.00%	91.00%	90.00%		95.00%
Specificity	92.00%	90.00%	88.00%		97.00%
Equipment cost	$15,000	$12,000	$25,000		$10,000
Equipment Footprint (sf)	9	10	12		4

Commercialization Pathway

Non-Therapeutic Examples:

Proof-of- Concept	Prototype Build & Test	Approval Studies	Commercialization
Design	Integration	FDA pre sub meeting	
Fabrication	Assembly	Clinical Trial	
Successful POC Data	Test		
Report of Invention to JHTV	Safety		
Patent Filing	Field test		
2018 - 2019	2020	2021	2022+
	Translational Funding		

Proof of Concept	Prototype Build & Test	Approval Studies	Commercialization
• Design • Fabrication • Patent Filing/Report of Invention • Successful POC data	o Field Test o Safety o Integration o Assembly	o FDA Pre-sub meeting o Clinical Trial	o Launch Product o Market
Grant Funding	Translational/Grant	SEED/Series A	SERIES A/B

	Proof-of-Concept	Prototype Build & Test	Approval Studies	Commercialization
Key Activities	Design Fabrication Successful POC Data Report of Invention to JHTV Patent Filing	Integration Assembly Test Safety Field test	FDA Pre-sub Meeting Clinical Trial	
Duration	2018 - 2019	2020	2021	2027+
Funding	NIH Grant Internal Funding	*____ Translational Funding	SBIR/STTR Seed Venture Capital Grant	Venture Capital

Therapeutic Examples:

Proof-of- Concept	Pre-clinical/IND Enabling	Clinical Studies	Commercialization
Experimental Design	GLP Manufacturing	Phase I Safety (X patients)	
Invitro Studies	Pharmacology	Phase II Dose (X patients)	
Successful POC Data	Toxicity	Phase III Efficacy (X patients)	
Report of Invention to JHTV	IND Preparation		
Patent Filing	FDA pre sub meeting		
2018 - 2019	2020	2021 - 2027	2027+
	Translational Funding		

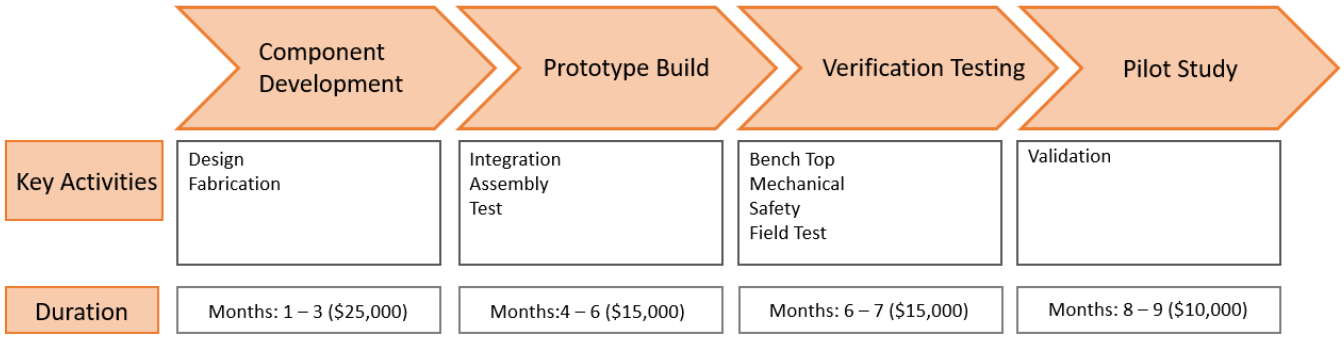
Proof of Concept	Preclinical Validation	Clinical Studies	Commercialization
• Experimental Design • In Vitro Studies • Patent Filing/Report of Invention • Successful POC data	o IND Preparation o Toxicity o Pharmacology o FDA Pre-sub meeting	o Submit for FDA approval o Phase I Safety o Phase II Dose o Phase III Efficacy	o Launch Product o Market
Grant Funding	Translational/Grant	SEED/Series A	SERIES A/B

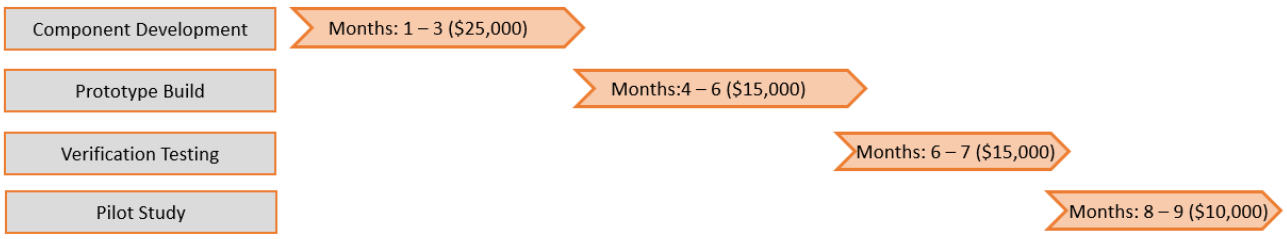
	Proof-of-Concept	Pre-clinical/ IND Enabling Studies	Clinical Studies	Commercialization
Key Activities	Experimental Design In-vitro Studies Successful POC Data Report of Invention to JHTV Patent Filing	GLP Manufacturing Pharmacology Toxicity IND Preparation FDA Pre-sub Meeting	Phase I Safety (X Patients) Phase II Dose (X Patients) Phase III Efficacy (X Patients)	
Duration	2018 -2019	2020	2021 - 2027	2027+
Funding	NIH Grants	*____ Translational Funding	SBIR/STTR Seed Venture Capital Grant	Venture Capital

Project Milestones

Component Development	Prototype Build	Verification Testing	Pilot Study
Design	Integration	Bench top	Validation
Fabrication	Assembly	Mechanical	
	Test	Safety	
		Field test	
Months: 1 - 3 ($25,000)	Months: 4 - 6 ($15,000)	Months: 6-7 ($15,000)	Months: 8-9 ($10,000)

Component Development	Months: 1 - 3 ($25,000)								
Prototype Build				Months: 4 - 6 ($15,000)					
Verification Testing						Months: 6-7 ($15,000)			
Pilot Study									Months: 8-9 ($10,000)





PROJECT BUDGET

BUDGET ITEMS	AMOUNT
Personnel	
Fellow (X months)	15,000
Graduate student (X months)	20,000
	35,000
Materials and Supplies	
Mechanical/Electrical components	5,000
Optical components	6,000
Miscellaneous (lab supplies)	3,500
	14,500
Other	
Regulatory Consultant	10,000
Lab Fees	8,000
Measurement Instrument	10,000
	28,000
TOTAL PROJECT BUDGET	**$77,500**