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# 1. Overview

## 1.1 Program Goals

The Fogarty Institute for Innovation is a 501(c)(3) educational non-profit whose overall goal is to support medical innovation, and thereby improve patient care. Through its Innovator Support program, the Institute works to achieve this goal by identifying and nurturing "pre-seed"-stage medical innovations that have significant potential to benefit patients. Prior to a true seed-stage financing event (typically \$0.2M-\$2M) is when an innovation can be the most fragile, with the fate of the innovation potentially turning on the timely availability of critical insight, encouragement, mentoring, and technical assistance. By providing all these ingredients at the earliest stages of development, the Fogarty Institute helps innovators develop the technical and business validation they need to attract seed stage financing from traditional sources (e.g. angels, VCs, and government grants). In the medical device field, these later stage investors, and the greater amounts of financing they can provide, are needed to move innovations into more advanced stages of development, commercialization, and eventual clinical application to benefit patients.

From our perspective, the need for the type of support provided by the Fogarty Institute's Innovation Support program is needed now more than ever. With the recent economic downturn, investors have become more protective of limited funds, more risk-averse, and demand greater validation of a technology before they will consider making even an early-stage investment. This creates a significant problem for innovators with breakthrough ideas, because they are finding it difficult to access funds needed to provide a preliminary validation, or proof-of-concept, of their idea. The Fogarty Institute is committed to identifying the most promising medical innovations, and providing them with the support they need to develop preliminary validation, and thereby attract seed-stage financing. By supporting the commercialization of innovation, we expect to benefit patients by providing them access to revolutionary medical technologies, and also benefit the regional and national economies by creating new companies and new jobs.

## 1.2 Program Eligibility

Please study the eligibility criteria summarized below, and only submit an application for innovator support if you meet these criteria.

**Fields of Interest.** The expertise of the Fogarty Institute mentoring staff lies in the area of medical device development, and therefore, at this time, we are only interested in supporting innovations in the medical device field. That being said, the medical device field is of course very broad, and includes devices useful in multiple therapeutic areas including cardiovascular, orthopedic, and general surgical, and we are interested in receiving applications relevant to all of these. At this time we are not asking for applications describing innovations in drug discovery, drug development, diagnostics, or genomics. This may change as we broaden our mentoring staff.

**Stage.** We are interested in supporting pre-seed stage innovations that are currently either unfunded, or that have received only modest funding. At this very early stage of your innovation development, and especially in the medical device field, the types and amount of support we can provide can make a difference to the success of your innovation, and your ability to develop the preliminary technical and/or business validation you'll need to attract your first financing. The Fogarty Institute Innovator Support program was not established to provide seed-round or A-round funding levels.

**Team.** We invite individuals or small groups (less than 5) to submit applications for Innovator Support. If you've already incorporated or formed an LLC, that's fine, and if you haven't yet

done that, we'll probably recommend that you do. The Fogarty Institute is not a VC or angel investor group, and so does not consider investments in established life science companies.

**Location.** To benefit from our ongoing mentoring process and our facility, you'll need to be where we are – in Mountain View, CA. Therefore, we require that at least one member of your team be located in Mountain View during the term of your support, and this person should be spending the majority of their time working on developing your innovation.

### 1.3 Types of Support.

We provide selected innovators with the support they need to attract seed-stage financing from traditional funding sources (e.g. angels, VCs, and government grants), and thereby rapidly proceed towards their goals of commercialization and patient benefit. For different innovators, this can mean different things. Some will need help designing and building an initial prototype, some will need help putting together a credible business plan, and many will need both of these things. In all cases, our mentorship team works personally with each innovator to provide the support needed to maximize the chances for success. Typically, innovators are supported for between 1 and 2 years by the Fogarty Institute, and we prefer applicants seeking support for time periods within this range. The Fogarty Institute offers three types of support to innovators, and these are described below:

**Mentoring.** The Fogarty Institute maintains a broad network of local, well-positioned experts, in fields relevant to the commercialization of medical devices, who comprise our mentoring team. Several of these experts are members of the Fogarty Institute staff, and others are members of outside organizations who have made a commitment to support medical innovation. Our mentoring team includes several world-class experts in the area of medical device development – including Dr. Fogarty himself. Other mentors provide expertise in essential areas such as corporate and patent law, regulatory issues, banking, financing, and business plan development.

**Facility.** The Fogarty Institute for Innovation maintains facilities on the campus of El Camino Hospital in Mountain View, California – located in the Silicon Valley region of the greater San Francisco Bay Area. Facilities available for use by innovators include a wet lab, dry lab, offices, conference areas, and engineering space. Further, our proximity to El Camino Hospital facilitates useful collaborations with physicians and hospital staff.

**Technical Assistance Funding.** Selected innovators will be offered technical assistance funding, which will allow acquisition of equipment, supplies, and expertise needed to develop preliminary technical and/or business validation of an innovation. Typically, the total amount of technical assistance funding we will consider providing is in the range of \$5,000 to \$20,000, and the exact amount will depend on the innovation, and what is needed to develop validation.

In exchange for receiving support from the Fogarty Institute, you will be required to present your progress at regularly scheduled innovator update meetings, commit to publishing scientific studies used to evaluate your innovation when appropriate, and participate in relevant Fogarty Institute events. Please only apply for innovator support from the Fogarty Institute if the types of support we provide would be of use to you.

## 2. Submitting an Application

### 2.1 Instructions

The process described below must be followed when submitting an application for innovator support to the Fogarty Institute. Applications or requests submitted via other mechanisms will not be considered.

- 2.1.1. **Step 1.** Read this “Application for Innovator Support – Instructions” document, and pay special attention to the Eligibility Criteria and Types of Support sections (Sections 1.2 and 1.3, respectively). Only submit an application if you are eligible, and if the types and magnitude of support offered by the Fogarty Institute would be useful to you. Applications not meeting the eligibility criteria and/or asking for support outside the scope offered by the Institute will not be considered.
- 2.1.2. **Step 2.** Download the [Application for Innovator Support – Form](#) document, and follow the instructions provided in Section 3, below, that describe how to complete this form. To open this application form, you will need to have [Adobe Acrobat Reader](#) downloaded on your computer.
- 2.1.3. **Step 3.** For each of your team members, create a cv with the following properties:
  - Word or pdf file format.
  - Four page maximum length.
  - Include separate sections summarizing education, work experience, honors, interests, and publications/patents.
  - Provide references to only the 10 most relevant publications and/or patents, and (if applicable) indicate the total number of publications/patents you have.
- 2.1.4. **Step 4.** Attach the completed Application for Innovator Support – Form document (Step 2) and all team cv’s (Step 3) to an email addressed to [applications@fogartyinstitute.org](mailto:applications@fogartyinstitute.org). Send this email to the Fogarty Institute with the following title in the subject field: “Innovator Support Application\_[last name of team leader]”.

### 2.2 Rules

**Number of Applications.** All individuals and teams are welcome to submit as many distinct applications as they wish, so long as the innovations described in the applications meet the eligibility criteria, and the types and magnitude of support offered by the Fogarty Institute would be useful for development of the innovation. Applications judged to be essentially identical to a previous application submitted by the same innovator will not be reviewed (except when errors are being corrected – see below).

**Application Document Naming.** As described in Section 2.1.4., submitted applications for innovation support must include both a completed version of the “Application for Innovator Support – Form” document and cv’s for team members, both attached to an email. Please name these required documents using the following naming conventions:

- Application for Innovator Support – Form: “Innovator\_Support\_Form\_[last name of team leader]\_[date as mmddyy]”.
- Team member cv’s: “Innovator\_Support\_CV\_[last name of team leader]\_[last name of team member (if applicable)]\_[date as mmddyy]”.

**Submission Deadlines.** At this time, the Fogarty Institute is accepting applications on an ongoing basis, and so applicants are welcome to submit applications at any time.

**Application Error Correction.** If, after the initial submission of an application, an applicant would like to make a correction to the content of the application (either the application form, or a cv), a corrected application may be submitted using the process outlined below:

- Make corrections to the document.
- Rename ALL application documents (both the corrected document, as well as documents not needing correction) using the naming conventions discussed above. Be careful to give all documents a name different from that used originally by using either a different date, or (if the correction is submitted on the same day as the original application) type the letter “c” after the date (e.g. mmddyc).
- Attach all application documents to an email addressed to [applications@fogartyinstitute.org](mailto:applications@fogartyinstitute.org).
- Send the email to the Fogarty Institute with the following title in the subject field: “Innovator Support Application\_[last name of team leader]\_correction”.

### 3. Completing the Application Form

#### 3.1 Overview

A completed [Application for Innovator Support – Form](#) must be submitted to apply for innovator support from the Fogarty Institute. This form is a pdf document, and so you will need to have [Adobe Acrobat Reader](#) downloaded on your computer to open it. The form asks for contact information, information about an applicant’s innovation, and information about the applicant(s) themselves. Please type your answers into the fields provided electronically using your computer, and DO NOT print the form out, write answers by hand, and scan the hardcopy document. We recommend that you save the form locally while you are working on it, and so have the ability to complete the form in multiple work sessions. The form enforces a character limit for each answer field, and so please compose your responses carefully, clearly, and concisely. If useful to you, you may format your responses by using **bold**, *italicized*, or underlined type. The form does not support the use of bulleted lists. Please follow the directions provided below when filling out the form. Forms incorrectly, incompletely, or unintelligibly completed will not be reviewed.

#### 3.2 Section 1: Applicant Contact Information

<b>Field Name</b>	<b>Instructions</b>
Leader Name	Write the name of the team leader, or individual innovator, using the format [first name] [last name]. For the purposes of this application, the team leader is the person who should be contacted regarding issues related to the application for support. In most cases, but not all, this will be the founder of the team.
Company Name	If you have a company name, please provide it here. Feel free to provide a name whether or not it pertains to a legally defined entity (e.g. a corporation, or an LLC). If you do not have a company name, write “n/a”.
Street Address	Write the street address belonging to your company, office, or residence (e.g. 123 Any St.).

<b>Field Name</b>	<b>Instructions</b>
City	Write the name of the city where you or your company are located.
State	Select from the drop-down menu the two-letter abbreviation for the state in which you or your company are located.
Zip Code	Write the 5-digit zip code area in which you or your company are located.
Phone Number	Provide a phone number where we can contact the team leader. Type the number in the format “2223456789”, and the form will automatically transform it into the format “+1 (222) 345-6789”.
Email Address	Provide an email address where we can contact the team leader. Type the email address in the format “name@domain.com”.
Website	If you have a website that describes your company or innovation, please provide it here. If you do not have a website, type “n/a”.

### 3.3 Section 2: The Idea

<b>Field Number</b>	<b>Instructions</b>
2.A.	<p><i>Q: What clinical need does your innovation address, and why is this need significant?</i></p> <p>Describe the clinical need that your innovation will address, and the therapeutic area for which the clinical need is relevant. Also, describe why this clinical need is significant. For example, because it has a high prevalence, and/or because there are no alternate solutions to the problem.</p>
2.B.	<p><i>Q: Provide a concise, yet detailed, description of your innovation, and describe any preliminary development work that you have already completed or is in progress.</i></p> <p>Describe the technology or process used in your innovation, and describe how, once developed, you envision your innovation being used in a clinical setting. Also, describe any preliminary work you’ve already done to develop your innovation; for example, prototype design, prototype construction, animal studies, business model development, etc.</p>
2.C.	<p><i>Q: Why is your idea innovative, and what is currently done to address the clinical need?</i></p> <p>Describe the novel methodologies, technologies, instrumentation, and/or applications embodied by your innovation. Also, briefly discuss current strategies and technologies available to treat the clinical need addressed by your innovation.</p>

<b>Field Number</b>	<b>Instructions</b>
2.D.	<p>Q: <i>What is the estimated market size for an eventual product resulting from your innovation?</i></p> <p>Provide an estimate for the annual U.S. and/or worldwide market size (i.e. number of patient uses per year) for your innovation. Support your estimate with data describing known patient populations and demographics.</p>

### 3.4 Section 3: The Development Plan

<b>Field Number</b>	<b>Instructions</b>
3.A.	<p>Q: <i>Outline the technology/business development plan you envision pursuing with the support of the Fogarty Institute to make your innovation investor-ready.</i></p> <p>Provide a brief outline of the technology and/or business development plan you propose pursuing with the support of the Fogarty Institute. Include milestones and time requirements in your outline. Also, include both technology and business development activities, as applicable, in your outline.</p>
3.B.	<p>Q: <i>What type(s) of mentoring support do you anticipate needing from the Fogarty Institute?</i></p> <p>Describe the types of mentoring support that you anticipate needing from the Fogarty Institute to make your innovation investor-ready. Please refer to Section 1.1.3 of these instructions for examples of types of mentoring support available. Please feel free to suggest additional types of mentoring support you would find highly beneficial to your project.</p>
3.C.	<p>Q: <i>What type of facility support will you need from the Fogarty Institute?</i></p> <p>Describe the amounts and types of facility support you anticipate needing at the Fogarty Institute. As applicable, include information on the number of people requiring lab/office space, and the types of lab space required by each (e.g. wet, dry, engineering, IT development, etc.).</p>
3.D.	<p>Q: <i>What amount of technical assistance funding do you request of the Fogarty Institute, and what will you use it for?</i></p> <p>Provide a listing of the items whose costs you will request be paid for by the Fogarty Institute. For each, describe the item, its importance to your development plan, and the cost. As described further in Section 1.1.3 of these instructions, the Fogarty Institute will consider providing funding for equipment, supplies, and labor/consulting costs critical to the completion of your innovation development project.</p>

### 3.5 Section 4: The Applicant(s)

<b>Field Number</b>	<b>Instructions</b>
4.A.	<p>Q: <i>For each member of your team, please list their name, email address, and functional role for your development project. List the primary contact (i.e. the team leader) first. Separate team members with a blank line. Place an asterisk in front of the name of anyone who would not be able to work at the Fogarty Institute if your application is selected, and please explain why not.</i></p> <p>Provide a listing of your team members. For each person, provide the information listed using the format indicated: [name: first, last]; [email address]; [functional role]. The team leader should be listed first, and information for each member should be separated with a blank line. By placing an asterisk (*) in front of their name, indicate any team member who would not be able to participate in your development project at the Fogarty Institute facility in Mountain View, CA, and please explain why not (e.g. family, school, etc.).</p>
4.B.	<p>Q: <i>What special experience or characteristics do you (or your team) have that will make you a successful medical innovator?</i></p> <p>Please explain why you (or your team) have the skills and characteristics needed to be a successful innovator. Please provide examples to support your explanation, and these may include examples directly related or not to past technology development activities.</p>

## 4. Review and Notification Process

Upon receiving your application package via email, members of the Fogarty Institute staff and mentoring team will review your completed application and cv's. On an ongoing basis, applicants judged to be especially meritorious will be invited to visit the Fogarty Institute for an interview. Whether or not you are invited for an interview, we will notify you of the status of your application within one month of its receipt. Final decisions to offer support will be made soon after applicant interviews.

## 5. Privacy Policy

During the application, interview, and selection phases of our process we will not sign an NDA; however, we will try, and it is our intention, to avoid disclosing your plans to potential competitors. Please review our [Privacy Policy](#).

## 6. Terms of Use

Please review our [Terms of Use](#) policy.