Sample NIH Entrepreneurship Bootcamp Request Form

The following document consists of fictitious responses to the registration questionnaire and is meant to provide guidance as to the minimum level of detail and specificity required for your submission to be considered responsive. These are not the "correct" answers, your responses should reflect current state of your proposed project as accurately as possible without embellishment. The example given here is for illustrative purposes only.

Business Lead (Required)

Name: **Mimi Morris, MBA**
Email: **MBMorris@Natcham.edu**

You must add email contact info for each team member

Technical Lead (Required)

Name: **Jonathan McCarthy, MD**
Email: JJ9@Natcham.edu

A Business Lead and Technical Lead are required to participate in the NIH Entrepreneurship Bootcamp

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Additional Team Member (optional)

Name: **Donovan N. Blake**
Email: **DNB72@Hang30.com**

Company/Team Name:

Gulo Gulo NCF

If you do not have a company, enter a unique name for your team. e.g. Duke University is not unique, Blue Devil Innovations is better.

Academic Affiliation (if applicable)

Concordia University

Please list any NIH award numbers you or your team members have received or been supported by, including any training grants or career development awards that are relevant to your proposed project, (no more than 3).

Award Number 1: **5R13AA112523**
Award Number 2:
Award Number 3:

If any of your team members have received NIH support, enter the most recent award here.
One per team member is sufficient.

Which of the following best describes the technology/products under development?

- ○ Biologic drug
- ○ Small molecule drug
- ✓ **Combination product (drug regulation)**
- ○ Combination product (device regulation)
- ○ Surgical device
- ○ Therapeutic device
- ○ Diagnostic device/tool
- ○ Diagnostic assay
- ○ Digital health
- ○ Education/training tool
- ○ Research tool
- ○ Other: _____

Select which areas your innovation may best fit with (select up to 3)

- [ ] Aging
- [ ] Alcohol Abuse/Alcoholism
- [x] **Allergies and Infectious Diseases**
- [ ] Arthritis, Musculoskeletal, Skin Diseases
- [ ] Biomedical Imaging/Bioengineering
- [ ] Cancer
- [ ] Child Health
- [ ] Deafness and Communication Disorders
- [ ] Dental/Craniofacial
- [ ] Diabetes, Digestive, Kidney Disorders
- [ ] Drug Abuse
- [ ] Environmental Health
- [ ] Eye
- [x] **General Medical Sciences**
- [ ] Heart, Lung, Blood
- [ ] Human Genome
- [ ] Mental Health

☐ Minority Health/Health Disparities

☐ Neurological Disorders/Stroke

☐ Nursing Research

Briefly describe the team members who will be participating in the Bootcamp program, identifying their roles and experience as it relates (Technical Lead, Business Lead) to the commercialization effort. Provide clear statements to indicate that all team members are able to meet the time-intensive requirements of the training program (expected to be 10-15 hours per week per team member for 6 weeks).

The Gulo Gulo NCF team participating in the NIH Entrepreneurship Bootcamp consists of three dedicated members:

Mimi Harris — As the Business Lead, Ms. Harris complements our team with over 10 years in executive experience in business development and strategic planning. As CEO, she has a proven track record in marketing, sales, and talent recruitment, vital for our project's commercialization phase. Most recently, Ms. Harris led drug discovery programs as a senior product development manager at Pfizer, Inc after previously worked in a similar capacity at Merck, Inc.

Johnathon McCarthy MD — As the Technical Lead, Johnathon brings extensive medical expertise as a clinician specializing in infectious disease and population health. He has a solid medical research and implementation science background, ensuring our project aligns with clinical adoption requirements. Over the past three years Dr. McCarthy has been the primary driver in the development of our NCF formulation, guiding our team of researchers through vigorous experimental trials to establish NCF as our lead indication.

Donovan N. Blake — Mr. Blake is CEO of Hang30 a startup accelerator who has acted as an advisor and executive coach to Gulo Gulo NCF in the development of our product. He leverages his prior experience as Chief Supply Chain Officer and Chief of Staff at Mednicator providing insights into operations management, supply chain logistics, and project management, which is crucial for navigating the commercial aspects of our venture. He was previously Deputy Chief of transport operations for Hart Package Delivery Inc.

Clearly describe the roles and responsibilities of each team member as it relates to your proposed project. Provide a brief synopsis of their relevant experience in biomedical product development or other entrepreneurship.

All team members are committed to dedicating 10-15 hours per week for the 6-week duration of the Bootcamp, ensuring we meet the intensive requirements of the program and successfully advance our commercialization efforts.

Describe the scope and nature of the problem you are trying to address.

Every fall thousands of young adults in the crowded conditions that prevail at college campuses across the country are subject to opportunistic infections from the bacterium Aesculus Glabra (A. Glabra). This insidious pathogen causes sporadic periods of delusional behavior, hallucinogenic perceptions and uncontrolled emotional lability in its most acute phases. While the infection normally resolves untreated, the effects can last several months and in extreme cases may become latent with relapses that recur annually. The impact of these outbreaks and their management is estimated to cost an affected campus between $100-$150 million annually.

Describe your proposed solution and innovation.

Your proposed solution must relate to the scientific mission of the NIH. https://www.nih.gov/about-nih/what-we-do/mission-goals

Gulo Gulo N.C.F. has developed a combination assay and biologic product derived from the epithelial cells of the Sus Scrofa Domesticus (SSD) that has documented success in arresting the advancement of A. Glabra in high density populations of college students, and reversing the toxic manifestations of the pathogen in infected individuals. The product consists of a proprietary assay for the targeted delivery of a SSD prolate spheroid, both with protected IP, designed to disrupt the mechanism of action of A. Glabra.

Define the impact that you hope to achieve using metrics most appropriate for you (eg: morbidity, mortality, time, efficiency, costs, etc.).

In developing NCF, the overarching goal is to achieve not only symptomatic relief but also a broader enhancement of patient quality of life and health economics. The efficacy and impact of NCF can be gauged through several key metrics. Firstly, reductions in the incidence of infectious outbreaks is the primary indicator of the drug's effectiveness. Secondly, the reduction in the severity of A. Glabra symptoms and the use of concomitant medications highlights the therapeutic's efficacy and can mitigate the risks of polypharmacy. Economic impact is evaluated via analyses that consider both direct and indirect costs, such as changes in work productivity.

Describe the current state of your IP as accurately as possible. This information will help your instructors guide you toward the correct commercialization pathways. It is not necessary to have a patent or other IP to participate in bootcamp.

Describe the status of your work and any disclosures or patent applications protecting your solution.

We have successfully demonstrated efficacy, biocompatibility, and safety in rodent and non-human primate models using cGMP-like materials. We are nearing completion of our second non-human primate studies and are determining the remaining necessary studies before pursuing pilot clinical trials. The formulation of the SSD prolate spheroid is protected by a series of patents filed in 2021. Gulo Gulo has secured the exclusive license for all relevant IPs associated with the composition and process for making NCF. We have been granted permission to by the Concordia tech transfer office to move forward with this technology as a startup.

Describe your current commercialization strategy and identify the key challenges that you hope the Bootcamp Program can help you address.

Gulo Gulo is targeting a variety of non-dilutive funding opportunities, including filing for additional grant opportunities, philanthropic organizations, and mission-based funds. Importantly, Gulo Gulo continues the early pursuit of developing strategic partnerships with large pharma and other strategic partners that would invest in and accelerate the development of our product. The goal of Gulo Gulo is to enter the market as quickly as possible, with the most robust development program feasible, and in the shortest and most cost-effective path possible. The company anticipates raising funding to support its current and future activities from pre-clinical through Phase 1 clinical trials. Given the large size and cost of clinical trials beyond Phase 1, the company will seek partnership with large pharma to support such activities toward drug approval and commercialization..

Our primary goal for the program is to leverage mentorship and advice from industry leaders and subject matter experts to accelerate our company's growth trajectory. Specifically, we aim to enhance our product development, refine our go-to-market strategy, and identify strategic partnerships to broaden our impact. With the program's guidance and resources, we believe we can expedite our path to market success and ultimately contribute significantly to the advancement of population health technologies and therapeutic development.

You have reached the end of the form. To submit your NIH Entrepreneurship Bootcamp Request Form, please click the forward arrow. If you would like to return to this form to edit, please copy the url and save it to return.