The following information is REQUIRED to process your research grant application. Please complete all application contents below.

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Note:

ESTA gives research grant proposals a scientific and healthcare compliance review, which takes approximately 21 days from the submission date. The proposals are reviewed to ensure that:

1) The subjects' well-being is of primary importance.
2) Medical and ethical concerns are raised and vetted.
3) Proposals are original and contribute to the body of knowledge.
4) The proposals are aligned with ESTA's educational, business, and/or research interests.
5) Proposals are likely to result in a publication or meet generally accepted public criteria.

Please submit all completed request, attachments AND a copy of your CV to:
grants@establishmentlabs.com

Part I: Submission Agreement

1. Agreement for submission of study concept information:

Investigator wishes to submit the idea described below for consideration by Establishment Labs. Investigator understands and agrees that this idea will be considered only under the terms and conditions set forth below and further agree that these terms and conditions shall also apply to any previous or future disclosures made by the Investigator which relate to the idea described herein.

1. Establishment Labs does not solicit suggestions, and all submissions or disclosures of ideas are voluntary on the part of the Investigator. No confidential relationship is established or implied by the Establishment Labs acceptance or consideration of the submitted material.

2. All suggestions will be submitted in writing and Establishment Labs shall have the right to retain any material submitted to it in connection with the suggestion.

3. Ideas that are not covered by a patent shall be considered by Establishment Labs only with the understanding that the use to be made of such ideas and the compensation, if any, are matters resting solely in the discretion of Establishment Labs.

4. Patented ideas shall be considered only with the understanding that the Investigator agrees to rely for Investigator's protection wholly on such rights as Investigator may have under the patent laws. Pending applications for a patent are to be treated in the same manner as ideas not covered by a patent, as described in paragraph 3, above, unless and until a patent issues.

5. Establishment Labs shall not be obligated to give reasons for its decision or to reveal its past or present activities relating to the submitted idea. Negotiating or offering to purchase an idea will not prejudice Establishment Labs nor be deemed an admission of the novelty, priority or originality of the idea.

6. All requests for financial funding must be consistent with Fair Market Value and will not be subject to any institutional overhead costs.

The disclosure which the Investigator makes relates to the attached Protocol or Protocol Concept.

Investigator represents and warrants to Establishment Labs that, except as noted herein, the material disclosed is wholly original with the Investigator; that no interest has been granted to or acquired by others; and that Investigator has full authority to make the disclosure and to execute this release.

2. Financial arrangements include the following considerations:

Disclosure Pursuant to Laws:
The Parties acknowledge that certain laws now or in the future may require, medical device to disclose information on compensation, gifts or other remuneration provided to physicians and other healthcare professionals. Establishment Labs may report information about remuneration provided under this Agreement, as required by law. Once reported, such information may be publicly accessible.

3. Privacy considerations:

By requesting a Research Grant, Investigator consents to the collection, use and disclosure of the information Investigator has provided, in accordance with this Privacy Statement. Investigator's name, address, email address and other personal information will be used by Establishment Labs to support our grant process. Establishment Labs may disclose Investigator's personally identifiable information to third parties, located in any country where required by applicable laws, court orders, or government regulations.

Investigator has the right to reasonable access to Investigator's personal information maintained by Establishment Labs, and the right to correct such information, as appropriate. It is the Investigator's responsibility to ensure the accuracy of Investigator's personal information. To keep personally identifiable information accurate, current, and complete, please contact Establishment Labs Compliance Department at grants@establishmentlabs.com

Establishment Labs is committed to protecting the security of the Investigator's personal information. Establishment Labs uses a variety of security technologies as well as procedures and take reasonable steps to protect the Investigator's personally identifiable information.

4. Affirmation

Investigator affirms that Investigator has no financial or proprietary interest in the product(s) being studied. Investigator affirms that Investigator and Investigator's Institution have not been prohibited by law from providing clinical research services and have not been convicted of a criminal offense related to the provision of health care items or clinical research.

Investigator affirmation: Investigator affirms that Investigator has read and concur with the above agreement.

Investigator Signee: Signature:

Print:

Date:

Part II: Applicant Information & Requested Support

Date	
Investigator (Name and Title)	
Institution	
Institution Address	
Relationship to Institution	○ Employee ○ Contract ○ Other, please specify:
Office Phone	
Business Email	
Preferred Contact	
Contact Phone	
Contact Email	

Collaborators (List if any):

Name	Study role

Financial Request Information

Select Currency:

	Type	Quantity	Cost
Total Project Cost			
Financial request from Establishment Labs			
Product request from Establishment Labs In			
Kind Service request from Establishment Labs			

List Key Budget Items (Cash Costs, not in kind services or product)	Cost

Please list any additional sources of support:

Is clinical insurance required? ○ Yes ○ No

Part II: Applicant Information & Requested Support

Please complete OR **Provide Study Synopsis** with this information.

Project Title:

Study Type: ○ Clinical Trial ○ Animal Study ○ Health Outcomes ○ Other

Study Driven by: ○ Pilot/Feasibility ○ Hypothesis

Study Design:
(Choose best option)

- ○ Randomized, concurrent control with blinding: ○ Single ○ Double
- ○ Randomized, concurrent control no blinding
- ○ Non randomized, prospective, concurrent control
- ○ Non randomized, prospective, no concurrent control
- ○ Case series, retrospective
- ○ Review published trials (meta-analysis)
- ○ Database mining
- ○ Other, please describe:

Estimated Start Date: Estimated Start Date:

Subject Visits: ○ Pre Treatment ○ During Treatment

1st Follow up visit on:

2nd Follow up visit on:

3rd Follow up visit on:

4th Follow up visit on:

Total Sample Size:

Treatment Subject Count:

Control Subject Count:

Primary Endpoint Responses:
(these are the estimates/assumptions for the group results in terms of the primary endpoint; for a binary endpoint report the proportion of subjects that are expected to succeed; for a quantitative endpoint report the estimated mean value)

Control Group:

Treatment Group:

Provide the constraints used for sample size determination:

Significance Level (alpha):

Power (1-beta):

Current Status:
Full protocol developed? ○ Yes (Attach if yes) ○ No

IRB/Ethics/Animal use committee status: ○ Not Submitted ○ Under Review ○ Approved ○ N/A (please explain):

Dissemination Plans:

- ○ Presentation, local/regional meeting Date:
- ○ Presentation, national/international meeting Date:
- ○ Manuscript suitable for submission to peer reviewed journal Date:

Describe Study Significance:

Describe Hypothesis:

Primary Endpoint:

Secondary Endpoints:

Inclusion Criteria:

Exclusion Criteria:

Study Procedures:

Steps to protect rights of study subjects:

References: