Sensor Technologies to Monitor Inflammation in Inflammatory Bowel Diseases

Request for Proposals (RFP)

Program Guidelines & Policies

Effective June 11, 2018

Crohn’s & Colitis Foundation
National Office
Research Department
733 Third Avenue
Suite 510
New York, NY 10017

Contact:
Dr. Andrés Hurtado-Lorenzo, Senior Director of Translational Research
E-mail: ahurtadolorenzo@crohnscolitisfoundation.org

Dr. Gerard Honig, Translational Research Manager
E-mail: mailto:ghonig@crohnscolitisfoundation.org

Tel: 800-932-2423 Ext. 5990 | 646-943-7479

MISSION:
To cure Crohn’s disease and ulcerative colitis, and to improve the quality of life of children and adults affected by these diseases.

Last revision 6-07-2018
## Key Dates

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>RFP Announcement</td>
<td>June 11, 2018</td>
</tr>
<tr>
<td>Application deadline</td>
<td>September 7, 2018</td>
</tr>
<tr>
<td>Anticipated funding notification</td>
<td>December 20, 2018</td>
</tr>
<tr>
<td>Anticipated start date</td>
<td>January 2019</td>
</tr>
</tbody>
</table>
1. Overview

The mission of the Crohn’s & Colitis Foundation is to cure Crohn’s disease and ulcerative colitis, and to improve the quality of life of children and adults affected by these diseases. In order to pursue this mission, the Crohn’s & Colitis Foundation regularly convenes thought leaders and stakeholders (such as patients and caregivers) to identify key barriers that need to be addressed in the field of inflammatory bowel disease (IBD) research (‘Challenges in IBD’). Through this process, the Foundation has recognized the necessity to advance research focused on novel technologies to address unmet clinical needs in IBD, particularly relating to continuous monitoring of inflammation in IBD. The present document summarizes the goals, scope and selection criteria for a new funding initiative to address this need.

2. Scope & Selection Criteria

The purpose of this initiative is to support the development of sensor technologies that can be implemented to detect and monitor inflammation in the context of IBD. Through this RFP, the Crohn’s & Colitis Foundation seeks to support research for the development of such technologies, particularly those that have the potential to reach clinical studies within the next 3-4 years. Proposals should meet the following criteria:

A. Relevance to monitoring of inflammation in IBD. Proposed sensor technologies must have the potential to detect and monitor inflammation in IBD patients. Collection of additional information potentially relating to IBD may be proposed; however, only projects that focus on the detection of active inflammation will be considered for funding. Preferably, the signals detected should be related to biological processes regarded to be causative and/or highly correlated with intestinal inflammation in IBD (e.g. cytokine levels, presence of proinflammatory immune cells, proinflammatory mediators, etc.) and should be informative with respect to symptoms (e.g. ability to detect an active ‘flare-up’ prior to observation of severe symptoms, or the ability to distinguish between symptoms caused by inflammation and symptoms occurring in the absence of inflammation).

B. Technology characteristics. The present RFP focuses on biosensors, meaning implantable, ingestible, wearable or environmental devices or nano-sensors with the potential to provide minimally invasive monitoring for detection of inflammation in IBD. Sampling of data should be continuous or periodic and should be real-time or near-real-time, and data reporting should integrate over a short enough period of time, to enable monitoring of physiological relevant fluctuations in the specific biological signal(s). In general, the proposed device should provide monitoring capability without the need for a visit to a healthcare facility; rather the technology should allow for routine monitoring during daily life. Preferably, feasibility of the proposed detection technology will have been demonstrated at the time of application through the generation of a functional prototype with demonstrable capability to detect signals relevant to inflammation in IBD. Proposed technologies should have the potential for practical, cost-effective and sustainable use. Ability to rapidly deploy in IBD patients in a patient-friendly format will be
preferred. Eventual feasibility to obtain appropriate regulatory compliance, if relevant for the proposed product, will be considered.

3. Eligibility

The Principal Investigator (PI) must be a faculty member actively conducting research in the area of interest of this RFP (sensor technologies for healthcare applications). If the PI does not have experience in IBD research, a collaborator(s) with experience in IBD should be identified as needed to support the project objectives. At the time of application, the PI must be employed by an institution (public non-profit, private non-profit, or government) engaged in health care and/or health related research. There are no geographical restrictions regarding research site location(s). Proposals involving multiple institutions are welcome; one institution should be identified as the prime applicant. US and international researchers are encouraged to apply.

4. Grant Funding Terms

Two independent awards will be granted for a project period of one year with a maximum amount of $125,000 per year, inclusive of all indirect expenses. Specific milestones will be agreed upon project onset; renewal of funding beyond the first year will be considered on a competitive basis for programs that achieve Year 1 milestones. Indirect expenses must not exceed 10%. Standard funding policies of the Crohn’s & Colitis Foundation will apply. All intellectual property generated through funded activities will be fully owned by the funding recipient.

5. Submission Guidelines

A. The application should include the following (Appendix A for details):
   i. Summaries (abstracts) of the proposed project (lay and scientific versions).
   ii. Brief description of how this project is explicitly related to IBD and how it aligns with the research priorities of this RFP.
   iii. Cover page describing background and expertise of the PI, and relevant investigators, and the role/tasks to be performed by each investigator.
   iv. Research proposal: specific aims, background, including rationale and preliminary data, experimental plan, and expected outcomes. These sections should not exceed 8 pages total.
   v. Budget specifying the total funds requested, budget justification, and a list of the current sources of funding held by the PI.
   vi. A short biosketch (4 - 5 pages maximum, NIH format) of the PI. Optionally, biosketches for other key collaborators may be included.
   vii. Timeline for completion of project (Gantt chart or similar format), including milestones by aim projected for every 3 months of the project period.
   viii. Letters of support (optional).
   ix. Bibliography.
Additional notes: The proposed research plan, budget and timeline should include a list of milestones, specified in intervals of approximately 3 months. Justification of the budget must be described. Alternative approaches and risk mitigation strategies should be included. Proposals should include preliminary evidence and justification supporting the feasibility of the technology and relevance to detecting inflammation in IBD.

6. Application Review

The investigators will provide a full research proposal and the accompanying document by the application deadline (see Key Dates, above) and according to the guidelines for proposal preparation and electronic submission (Appendix 1, below). The proposals will undergo peer review by a multidisciplinary review committee and evaluated based on the following criteria:

- Alignment with the scope for this RFP (see Section 2 above).
- Research strategy: The proposal should include preliminary data in support of the potential of the proposed technology to monitor inflammation in IBD. Specific aims and milestones should describe a focused, rigorous approach to validating and/or improving the application of the proposed technology to monitoring inflammation in IBD.
- The proposal must be well written and understandable by the scientific audience. The lay summary must clearly summarize the proposal and be understandable for non-scientific reviewer.
- Feasibility of success: Demonstration of capabilities, personnel and infrastructure to conduct the proposed study, organizational resources, collaborators.
- Investigators’ professional accomplishments: The PI must show a successful track record in acquiring funding and published research in the field of sensor technologies. At least one collaborator must have proven expertise in IBD research (basic and/or clinical).

7. Progress Oversight

Written scientific reports are required and must be submitted, using the Foundations standard progress report template, according to the following deadlines:

- 9 months post study initiation. Applicants should be aware that this progress report will be taken into consideration if the applicant chooses to apply for funding for additional activities following the completion of the one-year project.
- 15 months post study initiation (final scientific report). A financial accounting report will also be due at this time.

The PI will be also required to convene with the members of the review committee and Foundation staff once at the conclusion of the project period. During this face-to-face meeting, the PI will present and discuss the year findings with committee members. Expenses related to these meetings will be funded by the Foundation and they do not need to be included in the
project's budget. In addition to the in person meeting and written annual report, a teleconference will be required, to be held five months post study initiation, to include the PI, members of the review committee and Foundation staff, to report on progress of the project.

8. Submission Instructions for Proposal Central

A. All applications should be submitted through the proposalCENTRAL portal at the following URL: https://proposalcentral.altum.com/
B. Please complete all indicated sections
C. Review Appendix A for complete instructions of the electronic application process

9. Contact Information

For additional information please submit your queries to Dr. Gerard Honig, Research Manager: ghonig@crohnscolitisfoundation.org
APPENDIX A: Instructions for Electronic Application

General information

The full application is due on September 7, 2018.

The application should be submitted to proposal central at: https://proposalcentral.altum.com

Paper copies of the application are not accepted.

To start the application process, follow the steps below:

x. If you are a first-time user, register by clicking on “First time user.” This will generate a confirmation number which will be emailed to the email connected to this account. Confirm your registration by submitting this number when prompted.

xi. Once you are a registered user, please click on “Grant opportunities” on the far right of the page and select Crohn’s and Colitis Foundation under “Filter by Grant Maker” drop down menu on the upper left of the page.

xii. Locate the “Sensor Technologies in IBD” announcement and click “Apply now”.

xiii. To activate the navigation bar on the left, enter the title of your proposal on the title page and “save” the application. The navigation bar on the left will now become interactive for you to continue your application.

xiv. Once completed, please validate and submit the application.

Detailed Instructions for Electronic Submission

Title page

Enter your title and “save” the application

Templates and Instructions

PI Biosketch and a New Vendor Form are available for download.

New Vendor Form *Required (part of Attachments section)

Complete this form to authorize your institution to receive payment from the Foundation. This document contains the instruction on how payment will be transferred to your institution and should not include information on the Investigator. This is required even if institution has received Foundation funding in the past.
Enable other Users to Access the Proposal

Add personnel that can have access to review and edit the proposal.

Applicant /PI

Principal Investigator (PI) is defined as the one person responsible to report to the Foundation for scientific and technical direction of the project. Although a Co-PI could be included in the proposal, only one person can be indicated as the main point of contact. Note: If the research (entirely or partially) is to be conducted in the Co-PI’s laboratory, a subcontract budget needs to be proposed.

Institution and Contacts

Provide contact information of the signing staff officials at the institution where the lead PI is located and where the study will take place.

Key Personnel and Collaborators

Add the roles and the contact information key personnel and collaborators that you would like to include on this application.

Effort

Percentage estimation of amount of time allocated to this project: Describe how the time (in percentages of full time effort) is allocated in your current position at this institution.

Summary

Lay Summary

The Foundation has instituted a Patient/Caregiver Reviewer Program, in which selected lay patients participate as voting members of the various review committees. Your lay summary should be a clear, concise overview in simplified language, appropriate for non-scientific reviewers. You need to provide enough essential information that the Patient/Caregiver Reviewers will be able to evaluate your application. The lay summary should include the following information:

1. What question will this project attempt to answer?
2. Why is this question important to IBD?
3. What is the study design?
4. How do the hypothesis and specific aims fit with Foundation’s scientific priorities?
5. Will this research, if successful, further the Foundation’s mission to find the causes and cures of IBD and/or to improve quality of life for IBD patients? If so, how will this project do so?

Please note that a lay summary that does not fully address these questions and which is not clearly written using lay-accessible language could affect the score provided by the Patient/Caregiver Reviewer.

**Template for Writing the Lay Summary**

Investigator: Burrill Bernard Crohn, MD; Mount Sinai Hospital

Project: Gender differences in growth in pediatric patients with Crohn’s disease

**Description:** Growth failure is a unique and important problem for children with IBD. The exact causes of growth failure, and how best to treat them, is a pressing need. In children with Crohn’s disease, boys and girls differ in disease severity and growth failure. That is, female patients tend to have more severe clinical disease but don’t suffer from growth failure, while male patients tend to have less severe clinical disease and suffer from growth failure. Understanding the reasons for these differences could provide new clues on the reasons for disease severity and growth effects of IBD, and how better to treat them. This project tests whether sex hormones (estrogen in females, testosterone in males) act differently on the function of hormones controlling growth (growth hormone itself, Insulin-like Growth Factor-1 [IGF-1], and the pathway linking them). This project will study 90 pediatric Crohn’s patients under the age of 17, matched to a control group of patients with short stature alone (unrelated to Crohn’s disease), and determine whether disease activity affects growth hormone/IGF-1 levels, and how this affects growth in kids with Crohn’s.

Also include a brief glossary of any scientific terms included in your lay summary.

**Scientific summary of the Project**

Summary should provide a clear, concise overview of the proposed work, including the background, objective, or hypothesis and its supporting rationale; specific aims of the study for general scientific audience.

**Budget Period Detail**

Start and End Dates

Specify date on which you expect to start this project.

Complete the e-form total budget.
The budget requested per year may not exceed $125,000 inclusive of indirect cost (Direct costs: $113,542; indirect costs: $11,458).

**Budget Summary Detail**

The total budget request for year 1 must not exceed $125,000 inclusive of 10% indirect cost. Salaries are capped at NIH limits.

**Current and Pending Financial Support**

Please provide information on additional ongoing funding that currently supports this research project.

**Organization Assurance**

**Human/Animal Studies Approval/Recombinant DNA**

All activities involving human subjects or vertebrate animals must be approved by an appropriate institutional review board (IRB) or equivalent prior to the start date of award. Indicate with “Yes” or “No” response, and if yes indicate date of approval and attach approval in that Attachments Section.

Copies of the IRB approval should be provided to the Foundation’s Research Department. If approval is not available at the time of application, provide a date of anticipated approval. This approval must be received before the start date of the approved grant.

**Upload Attachments**

Attachments (as described in Section 5 and below) should be converted to PDF format and uploaded using the proposalCENTRAL portal.

**Cover page**

Describe background and expertise of the PI, and relevant investigators, and the role/ tasks to be performed by each investigator.

**Research Plan/Protocol (Required)**

The description of the proposed research project must include the following items in sufficient detail to permit evaluation of the scientific merit of the study. This cannot exceed 8 pages, single spaced. The page limits distribution indicated below are included as a guideline and not required.

- Overall Objectives and specific aims
  - Briefly outline the general scientific objectives
Describe concisely and realistically what the specific research described in this application is intended to accomplish.

**Background** - including preliminary data
- Outline the previous work in the area by others, and the preliminary data or previous studies by the investigator(s). Enough preliminary data should be included in the application to demonstrate that the project is feasible and that the investigator is likely to complete the project successfully in the duration of the grant.

**Detailed description of methods and materials to be used**
- Provide a detailed discussion of the experimental design, procedures, and materials to be used to accomplish the Specific Aims.
- Describe protocols, including methods for new techniques, and explain the advantages over existing methodologies.
- Discuss the kinds of data expected to be obtained and how data will be analyzed and interpreted.
- Justify the use of any animal models (i.e., choice of species, number used, etc.).
- Discuss potential difficulties and/or limitations of the proposed procedures and alternative approaches to achieve aims.

**Significance and relevance of the proposed research to Crohn's disease and/or ulcerative colitis**
- Justify the significance of the results of this project to monitoring of inflammation in IBD.

**Facilities available to carry out the proposed studies**
- Describe the facilities available, including square footage, equipment, animal care facilities, and other environmental factors. Pay attention to those items required for successful completion of this proposal. Include a description for each facility to be involved.

**References**
- Literature citations should be listed in this section, at the end of the Research Plan. ***This is not counted towards the page limits.

### Formatting the Application

Applicants must adhere to the following instructions in completing the proposal sections that make up the electronic version of the application.

1. Please remember to insert your name in the header on each form in the attachment section.
2. Font size: Use 11 point Times New Roman or 10-point Arial as the minimum font size for the text of the application. A 9-point Times New Roman or 8-point Arial font type may be used for figures, legends, and tables.
3. Single-spaced text is acceptable, and space between paragraphs is recommended.
4. Margins: The margins of your text should be at least 1” inch on all sides, unless a form with different margins is supplied in the Application Templates or Forms.
Timeline and Milestones (1 page)

Timeline for completion of project (Gantt chart or similar format): List of milestones projected for every 3 months of the project period.

Milestone-driven budget summary table (1 page)

Summary of expenses broken down by specific aim / milestone. When Foundation funding would be supplemented by additional funds from another source applied towards project objectives (cost sharing), such funding may be indicated (in a separate column). Project related overhead may be included in proposed Foundation funding but must not exceed 10% of total funding provided.

Biosketches for Key Personnel

Biosketch (NIH format) for PI (required) and additional key personnel (optional).

Letters of Collaboration

Attach supporting letter(s) (optional).

References/ Appendices (optional)

Uploaded reference material may include, but not limited to:

1. Article references
2. Abstracts
3. Original Pictures
4. Other Letters of Support

Human and/or Animal Approvals - Optional

Upload IRB approvals for human and animal research

Signed Signature Pages

This document is generated by the PDFs and Signature Pages module after submitting all the forms and uploading all the required documents. Module PDFs and Signature Pages are located on the navigation bar on the left hand side.

Validate
Click **Validate** to check for any missing REQUIRED information or files. All missing required information will be listed on the screen.

**PDFs and Signature Pages**

Click **Print Signature Pages** to be signed by the applicant and the organization officials. Upload the signed document on the Upload Attachments module.

Click **Print Signature Pages and Attached PFD Files** if you would like to save the full application for your records. Do not upload the full application with the signed signature pages in Upload Attachment module.

**Submit**

Only the primary PI is authorized to submit the application.