

**CROHN'S & COLITIS FOUNDATION OF AMERICA**

**Senior Research Award**

**INSTRUCTIONS**

**Effective May 2011**

**Crohn's & Colitis Foundation of America  
National Office  
Research & Scientific Programs Department  
386 Park Ave South – 17<sup>th</sup> Floor  
New York, NY 10016-8804**

**Voice: 800-932-2423 Ext. 7501  
646-943-7501**

**Web site: <http://www.ccfa.org>  
E-mail: [grants@ccfa.org](mailto:grants@ccfa.org)**

**MISSION:**

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

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## GENERAL INFORMATION

### **Deadline and Submission Requirements**

IGAM (Internet Grant Application Module) is hosted on a web browser on the Crohn's and Colitis Foundation of America (CCFA) web site. Access is available using links provided at [ccfa.org](http://ccfa.org).

Each applicant needs to submit a letter of intent (LOI) prior to sending a full application. The letter of intent (LOI) allows CCFA to estimate the potential application review workload and to avoid conflict of interest at the review study session. **The letter of intent is mandatory.** The electronic LOI must be submitted by close of business (5:00pm EST) on the submission deadline, November 1 or May 1. LOI links will open 1 month prior to the submission deadline.

If your LOI is approved, you will receive an e-mail with the link to submit a full application. The master (paper copy) of full application with **original signatures** must be sent to CCFA and be postmarked on or before the submission deadline of July 1 or January 14. See further instructions "Assembly and Submission of Paper Copy" on Page 4.

Once submitted, you will receive an e-mail confirmation. If you have not received this within 48 hours of submission, please contact the help desk. If it is determined that some part of the application was lost or did not transfer correctly during the submission process, CCFA has the option to "Reject" the application. If you are unsure, please contact the help desk to ensure that the issues are addressed and corrected.

**If you have questions regarding the electronic process, go to our website for our [online tutorial](#) or contact the CCFA by phone at 646-943-7501 or via email at [grants@ccfa.org](mailto:grants@ccfa.org).**

### **Application Timetable**

Letter of intent to apply due	November 1*	May 1*
Full Online Application due	January 14*	July 1*
Submission of Paper Copy	Postmarked January 14*	Postmarked July 1*
Review	mid April	mid November
Board of Trustees	mid April	mid November
Start Date	July 1	January 1
Progress Report Due	April 1	October 1

\*Should the deadline date fall on a weekend or national holiday, the submission deadline will be extended to the following business day.

### **Formatting the Application**

Applicants must adhere to the following instructions in completing the proposal sections that compose the electronic version of the application. Failure to observe font size specifications and/or page limits will result in rejection of the application without review:

- Please insert your name in the header on each form in the attachment section.
- Font size: Use 11-point Arial as the minimum font size for the text of the application. A 10-point Arial font type may be used for figures, legends, and tables.
- Single-spaced text is acceptable, and space between paragraphs is recommended.
- Margins: The margins of your text should be at least .5" inch all around, unless a form with different margins is supplied in the Application Templates or Forms.
- Fill in all required fields (\*)

## File Size

**Important! File Size Limit:** Most Foundations limit the size of the files they will accept. The purpose for limiting file size, as well as page limits, is to facilitate review of the application. Very large files can make a full and comprehensive review of the application extremely difficult as many of our review panel members must download your PDF uploads. Therefore, **uploaded PDF files can be no larger than 25 MB.** The objective is to find a balance between the content of your application and file size.

## Uploading Documents- Naming Format

The paper copy (master) of the full application must be postmarked no later than the deadline date (July 1 or January 14) to the Crohn's & Colitis Foundation National Office. The paper (master) copy of the full application must contain assembled in this order:

- Last name, First name – Research Plan or Protocol
- Last name, First name – Detailed Budget Pages for Year 1 -3
- Last name, First name – Letters of Support/Collaboration
- Last name, First name – Signature page
- Last name, First name – Applicant's Research Experience
- Last name, First name - Applicant's CV/NIH Biosketch
- Last name, First name – Proof of Work Status
- Last name, First name - Resubmission Materials
- Last name, First name – References/ Appendices
- Last name, First name – Human & Animal Approvals
- Last name, First name – Abstract for Pending Application(s)
- Last name, First name – Electronic Transfer

**All attachments must be uploaded as .pdf documents.**

## Assembly and Submission of Paper Copy

The paper copy (master) of the full application must be postmarked no later than the deadline date (July 1 or January 14) to the Crohn's & Colitis Foundation National Office. The paper (master) copy of the full application must contain assembled in this order:

- Application Forms
- Budget Pages
- Justification of Personnel Budget
- Research Plan (Protocol)
- Letters of Collaboration
- NIH Biosketch for PI
- Applicant Research Experience
- Human & Animal Approval (optional)
- Resubmission
- Signature page (**original signatures**)
- Appendices (optional)

Mail to:

Crohn's & Colitis Foundation of America  
National Office- Research & Scientific Programs Department  
386 Park Ave South – 17FL  
New York, NY 10016

Note: Faxed or e-mailed submissions will not be accepted. No supplemental materials will be accepted after the submission deadline unless requested by staff for administrative purposes or requested by the reviewers for clarification.

## Help Desk Information

For any questions or concerns please contact the CCFA Research helpdesk:

Telephone: 646-943-7501

Email: [grants@ccfa.org](mailto:grants@ccfa.org)

## **LETTER OF INTENT**

(stage 1 of the application process)

Each applicant must submit a letter of intent prior to sending a full application. The Letter of Intent is mandatory.

The letter of intent is due on either of the following deadlines: November 1 or May 1. **Access to the electronic version will be closed by 5:00pmET on either deadline.**

Resubmitted applications do not require a letter of intent.

### **Eligibility Quiz**

You are required to complete an eligibility quiz. Your answers will determine if you are eligible for a CCFA Senior Research Award and if you can continue with the LOI process.

FILL IN TEXT BOXES FOR ALL OF THE FOLLOWING:

- Select degree that best match your credentials
- Employed by health organization within the U.S.
- Type of organization
- Independent of a mentor
- If MD applicant, 2 years post-doctoral experience in IBD
- If PhD applicant, 1 year post-doctoral experience in IBD

### **Contact Information**

#### **Principal Investigator**

PI is defined as the one person responsible to the Foundation for scientific and technical direction of the project.

FILL IN TEXT BOXES FOR ALL OF THE FOLLOWING:

- Name: FIRST name, MIDDLE name, LAST name
- Degree:(e.g. M.D., Ph.D.)
- Academic Title
- Address: Complete mailing address for correspondence to the applicant
- City, State, Postal Code
- Telephone: The phone number at which you are most likely to be reached during the day.
- Fax and E-mail

#### **Organization Information**

This is the location of where the PI is located and where the study will take place.

FILL IN TEXT BOXES FOR ALL OF THE FOLLOWING:

- Organization Name
- Address
- City, State, Postal Code
- Phone and Fax
- Tax ID

### **Abstract**

**Type of Support**

Select the following Option:

- Senior Research Award

**Type of Disease**

Select one of the following Options:

- Crohn's Disease
- Ulcerative Colitis

**Project Title**

Fill in the project title. Do not use abbreviations unless absolutely necessary.

**Scientific Summary of Project**

The Scientific 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 the general scientific audience. This should be no more than one-half page.

**Relevance of the Project to IBD**

Provide a description of how this project is explicitly related to IBD and how it will further both research and CCFA's mission. This should be no more than one-half page.

*Note: Lay reviewers actively participate as voting members in the peer-review process. These individuals will look specifically for the relation of the study to IBD as well as the potential for applicants to continue their careers in IBD research. It is the applicant's responsibility to clearly describe these aspects in easily understandable language for the lay reviewers. Failure to do so may result in a lower recommended priority score.*

**Attachments**

Please upload the following to this section

The Principal Investigator's name should be in the upper right-hand corner of each uploaded .pdf page

- NIH Biosketch
- Reference (optional)

**\*\*NOTE: Paper copy of your Letter of Intent is not required.**

## **FULL APPLICATION**

(stage 2 of the application process)

The full application is due on either of the following deadlines: July 1 or January 14. **Access to the electronic version will be closed by 5:00pmET on either deadline.**

Complete the electronic version of your application as follows:

Below you will find detailed instructions on completing these various sections. You will also find instructions on compiling the paper copy of your application for submission. **All application attachments must be uploaded as .pdf documents.**

**Some of the required information will have been automatically filled in from your Letter of Intent submission**

### ***General Information:***

#### **Type of Support**

Select the following Option:

- Senior Research Award

#### **Type of Disease**

Select one of the following Options:

- Crohn's Disease
- Ulcerative Colitis

#### **General Area of Research**

Indicate the scientific area(s) of your project.

Select 3 categories from the drop down box

#### **Challenges Priority**

Donors frequently have an interest in funding particular types of IBD research. Please check one Priority Area that is addressed by your project.

#### **Project Title**

Fill in project title. If this is a resubmission, the title should be the same as the original application.

#### **Principal Investigator**

PI is defined as the one person responsible to the foundation for scientific and technical direction of the project. Only one (1) principal investigator will be accepted on a proposal; co-investigator designations are not allowed.

FILL IN TEXT BOXES FOR ALL OF THE FOLLOWING:

- Name: FIRST name, MIDDLE name, LAST name
- Degree:(e.g. M.D., Ph.D.)
- Academic Title
- Gender
- Ethnicity
- Nationality: If none- US Citizen, Fill in information regarding Visa Work Status
- Institution Name
- Address: Complete mailing address for correspondence to the applicant
- City, State, Postal Code
- Telephone: The phone number at which you are most likely to be reached during the day.
- Fax and E-mail

## **Organization Information**

This is the location of where the PI is located and where the study will take place.

FILL IN TEXT BOXES FOR ALL OF THE FOLLOWING:

- Organization Name
- Address
- City, State, Postal Code
- Phone and Fax
- Tax ID
- Website (www) URL

## ***Abstract***

### **Resubmissions**

**(Leave this section blank if application is new)**

Applications that are not funded may be revised and resubmitted no more than 2 times. All resubmissions are competitively reviewed. Any resubmission of a previously submitted proposal should carry the same title as the previous application.

PROVIDE THE FOLLOWING INFORMATION:

- Number of times grant has been submitted  
Cannot be resubmitted more than 2 times
- Previous Submission date (Leave this section blank if application is new)  
Enter here month, day and year of previous submission
- Previous Submission Score (Leave this section blank if application is new)  
Enter score received for previous submission

**Upload all of the above in the Resubmission Section of the attachment section**

## ***General Information Regarding the Study***

### **Scientific Summary of Project**

The Scientific 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. This should be no more than one-half page.

### **Lay Summary**

CCFA has instituted a Stakeholder Reviewer Program, in which selected lay people participate as full 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 Stakeholder Reviewers will be able to evaluate your application. The lay summary should be no more than 1-2 pages and include the following information:

- What question will this project attempt to answer?
- Why is this question important to IBD?
- What is the study design?
- How do the hypothesis and specific aims fit with CCFA's scientific priorities?
- Will this research, if successful, further the CCFA'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?

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

*Note: Lay reviewers actively participate as voting members in the peer-review process. These individuals will look specifically for the relation of the study to IBD as well as the potential for applicants to continue their careers in IBD research. It is the applicant's responsibility to clearly describe these aspects in easily understandable language for the lay reviewers. Failure to do so may result in a lower recommended priority score.*

**This statement will be evaluated as part of your application as well as used to inform the Foundation's National Board of Trustees and the general public of the natures of this work; therefore, do not include proprietary or confidential information.**

Pointers:

- This section must be written in language that is easily understandable to a 6th-7th grade reader.
- Define all scientific terms; Words like "pathogenesis" or "cytokines" might be common words to you, but not necessarily to lay persons.

### **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

**Type of Award:** Career Development Award

**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 affects 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.

**Significance:** If successful, this project will establish whether a combination of sex and growth hormone levels can be used to predict growth failure. This information could help identify children with different biologic types of growth failure, and guide the development of more targeted treatments to correct them.

**Relevance of the Project to IBD:** Use our [Challenges Comparison Worksheet](http://www.cafa.org/ccfaprof/research-grant-ops/) on our website at <http://www.cafa.org/ccfaprof/research-grant-ops/> to find out which CCFA scientific priority listed is addressed by your project (choose one only).

### **Human/Animal Studies Approval**

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 to the CCFA National Office should be sent by mail. 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.**

### **Research Support**

Do you currently have financial support from other research projects? Provide information on all current research project and grants held by you and your staff. Include the following:

- Name
- Dates of Project (start and end)
- Current or Pending (dollar amount)
- Project Title
- Specifics Aims

At the time of review if the committee feels there is potential overlap; CCFA will request further details to clarify their concerns.

### **Pending Support**

Do you have any pending research support? Provide a list of all applications you are awaiting support. Include the following:

- Project Title
- Agency

### **Grant Administration Information**

In the event an award is made, provide the name and address of the person, at the grantee institution, whom will administer the grant.

FILL IN TEXT BOXES FOR ALL OF THE FOLLOWING:

- Name: FIRST name, LAST name
- Organization Name
- Address
- City, State, Country, Postal code
- Telephone
- E-mail

## **Budget**

Download the Detailed Budget templates from the form section of our web site and save to your hard drive. Complete budget page(s) then fill in the total budget for years one to three for PI and all other personnel on the e-form. Note the total budget request per year may not exceed \$128,700 (\$117,000 direct and \$11,700 for indirect). The budget pages will also need to be uploaded as an attachment in the attachment section provided. (Additional detail on budget information is provided in the attachment section under Detailed Budget). Please fill out the following fields:

- Direct Cost First Year
- Indirect Cost First Year
- Total Cost First Year
- Direct Cost Second Year
- Indirect Cost Second Year
- Total Cost Second Year
- Direct Cost Third Year
- Indirect Cost Third Year
- Total Cost Third Year
- Total Support Requested for Entire Project Period

## **Attachments**

Please upload the following to this section

\* Indicates Required

## **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 should not exceed 12 pages, single spaced.

1. Overall Objectives (one or two paragraphs)
  - Briefly outline the general scientific objectives
2. Specific aims (no more than 1 page)
  - Describe concisely and realistically what the specific research described in this application is intended to accomplish. Specifically outline Aims for year 1, year 2 or year 3, goals, deliverables and timelines. State any hypotheses to be tested.
3. Background -including preliminary data (no more than 4 pages)
  - 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.
  - If this is a renewal application, include a copy of your most recent progress report here (Progress Report is not counted as part of the six pages).
4. Detailed description of methods and materials to be used (no more than 6 pages)
  - 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 the means by which 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.

5. Significance and relevance of the proposed research to Crohn's disease and/or ulcerative colitis (no more than 1 page)
    - o Justify the significance of the results of this project to the understanding of the etiology, pathogenesis, therapy, and prevention of IBD. Specifically identify the gaps this project is intended to fill.
  6. Facilities Available to carry out the Proposed Studies (one or two paragraphs)
    - o Describe the facilities available, including square footage, equipment, animal care facilities, and other environmental factors. Pay particular attention to those items required for successful completion of this proposal. Include a description for each facility to be involved.
  7. Pertinent References (no more than 3 page)
    - o Literature citations should be listed in this section, at the end of the Research Plan.
- \*\*\*These are not counted as part of the 12 page limit.

Research Plan Section	Page Limit
Overall Objectives	½ Page
Specific aims	1 Page
Background -including preliminary data	4 Pages
Detailed description of methods and materials to be used	6 Pages
Significance and relevance of the proposed research to Crohn's disease and/or ulcerative colitis	1 Page
Facilities Available to carry out the Proposed Studies	½ Page
Pertinent References	3 Pages (not part of Research Plan)

### NIH Biosketch \*Required

Upload the NIH Biosketch for PI, Collaborators and Consultants

### Detailed Budget Forms for Year 1-3 \*Required

Download the template from the [SRA](#) section of our web site and save to your hard drive.

FILL IN TEXT BOXES FOR ALL OF THE FOLLOWING:

#### Pages 1, 3 and 5 (Years 1-3)

- Name of all personnel involved in the project
  - o List all personnel, both salaried and non-salaried. Also note that for every collaborator or consultant listed, there should be an accompanying letter of collaboration signed by them and must be listed on the Justification of Personnel Budget form(s).
- Percent Effort for all personnel involved in the project
  - o Indicate the percent of time each person will devote to this proposed project calculated from his/her total professional work hours based on a 40-hour work week on Justification of Personnel Budget form(s).
- Salary for all personnel involved in the project
  - o Salary support is not considered for students, fellows or trainees.
- Fringe Benefits for all personnel involved in the project
- Supply Costs
  - o List itemized supplies (such as animal boarding, molecular reagents, lab supplies) by category and total on the Detailed Budget for year 1; year 2; and year 3 (provide description of the supplies budget on the 2<sup>nd</sup> sheet of the budget form)
- Equipment Costs
  - o List any requests for equipment on the Detailed Budget for year 1; year 2; and year 3 (provide description of the equipment budget on the 2<sup>nd</sup> sheet of the budget form)
- Miscellaneous Costs

- List miscellaneous items (i.e., subcontracts, patient costs, etc.) and total on the Detailed Budget for year 1; year 2; and year 3.
- Travel Costs
  - List travel expenses (travel to DDW, etc) and total on the Detailed Budget for year 1; year 2; and year 3 (provide description of the travel budget on the 2<sup>nd</sup> sheet of the budget form) Total Direct Costs
- Total direct costs (salary, supplies, personnel, etc.) per year for Senior Research Awards may not exceed \$117,000
- Total Indirect Costs:
  - You may calculate up to 10% of total direct costs. This should be according to your institutional policy, but not exceeding 10% of the total direct costs (a maximum of \$11,700)
- Total Budgetary Request for Year 1; Year 2; & Year 3:
  - List total direct and indirect costs
- Total Budget for All Years
  - Total the direct costs for Salaries, Fringe Benefits, Equipment, Supplies, Travel and Miscellaneous Expenses and enter in the text box on the electronic form (i.e. total all salary requested for year 1 and enter in text box, and so on)

**\*\*\*Note on Subcontracts** If any portion of the proposed research is to be carried out at another institution, enter the total costs and provide a categorical breakdown of costs using duplicate copy(ies) of the grant application Detailed Budget for Years 1-3 and Justification of Personnel Budget pages. A letter of Agreement pertaining to the subcontract should be included in the Appendix. Note: indirect costs for the subcontract budget may be claimed by either the primary or secondary institution, but not by both.

#### Page 2, 4 and 6 (Years 1-3):

- Budget Justification: Supplies:
  - Itemize supplies by category (in text box of e-form) (i.e., glassware, chemical, etc.). Justify the request for supplies, including the quantity.
- Budget Justification: Equipment:
  - Itemize and justify (in text box of e-form) the need for any equipment requested for the proposed project, as well as why the equipment is being requested through funds from the CCFA instead of institutional funds. (Note the equipment policy in the Budget section of the Policies.)
- Budget Justification: Miscellaneous Expenses:
  - Itemize and justify any miscellaneous expenses (in text box of the e-form). These are any expenses that do not fit clearly into any other category (i.e., patient costs, subcontracting, etc.). If you are subcontracting, upload a detailed budget for that contract arrangement on the attachment section.
- Budget Justification: Travel:
  - Itemize and justify any travel expenses (in text box of the e-form). State the purpose of travel the number of trips and destinations (i.e., the meeting name), and the significance of the travel to the proposed project.

**\*\*Note the total budget request per year may not exceed \$128,700 (\$117,000 direct and \$11,700 for indirect). The final numbers for each year must be in the application form on the budget page.**

#### **Justification of the Budget \*Required**

Download the template from the [SRA](#) section of our web site and save to your hard drive. Complete budget page(s) then fill in the total budget for years one to three for PI and all other personnel on the form.

FILL IN TEXT BOXES FOR ALL OF THE FOLLOWING:

- Name
- Title
- Percent Effort
- Salary for each year
- Fringe Benefits for each year
- Percent Fringe benefits for each year
- Description of their role in the study

**Authorized Signatures \*Required**

Download the signature templates from the form section of our web site and save to your hard drive. These forms need to be completed and uploaded on the attachment section provided. The forms can be found in the form section of the CCFA web site. The original signatures must be included in the paper (master) copy of the application sent to CCFA. Be sure to include signatures for the applicant and institutional official.

**References/ Appendices- Optional**

A letter from the applicant's department chairman guaranteeing protected research time commensurate with the percentage of effort/salary to be devoted to the research project.

Upload all reference material this can include, but not limited:

- Article references
- Abstracts
- Original Pictures

**Letter of Collaborations- Optional**

Upload all Letters of Collaborations. There should be a letter of collaboration from all co-PI's, collaborators and consultants.

**Resubmission Material \*Required if this is A Resubmission**

Please follow these guidelines when resubmitting an application:

- "Reply to Previous Review", letter not to exceed 3 pages. The letter should clearly and succinctly address the points raised in the previous review and direct the reviewer to the specific sections of the Research Protocol where revisions have been made. Revised portions of the text changed in response to the reviewers' comments should be highlighted (e.g.: bold type, line in the margin, underlined, etc.).
- Scan and attach copies of the following
  - Critiques (Summary Statement) of the original application
  - Budget pages of previous application
  - Overall objectives and specific aims of previous application

Upload all documents to this section.

**Electronic Transfer- Optional**

Download the template from the form section of our web site and save to your hard drive. This is if you would like to have all your payments made electronically.

**Human and/or Animal Approvals- Optional**

Upload approvals for human and animal research

**\*\*\*PLEASE FOLLOW THE INSTRUCTIONS FOR NAMING ALL ATTACHMENTS\*\*\***

## **SPECIAL INSTRUCTIONS**

Applicants falling into any of the following categories should read the "Special Instructions" section pertaining to them before attempting to complete the application:

- Foreign Applicants
- Clinical Trials

### **Special Instructions for Foreign Applicants**

Complete budget request must be in U.S. dollars - **We will NOT convert.**

Please be aware that you should give more details than you might be accustomed, especially in the areas of background material and preliminary data, experimental design, and available facilities, budgetary items (particularly percent of effort and salary requests for key personnel).

**\*\*\*ALL MATERIALS AND REPORTS MUST BE IN ENGLISH. FAILURE TO DO SO WILL RESULT IN A REJECTED APPLICATION**

### **Special Instructions for Clinical Trials**

The Research Plan will need to include everything required in the Application Preparation section, plus the following information:

#### **Specific Aims:**

These should include a delineation of the primary and secondary end points to be measured with an appropriate explanation of the relative importance of the various end points.

#### **Significance:**

The application should clearly state the need for the study and how the results would impact on the prevailing practice in this area.

#### **Experimental Design and Method:**

The inclusion and exclusion criteria should be listed, and the procedure(s) to be utilized for assignment of patients to experimental groups should be described. The study design for the interventions to be used should be presented in detail including the rationale for the particular design chosen and procedures to assure compliance with and implementation of the proposed protocol. Potential biases in the proposed protocol and how they will be addressed should be presented.

Clinical, laboratory, and physiological tests should be described including methods of randomization. Finally, assumptions and calculations to arrive at the proposed sample size should be included.

The availability of patients for the proposed study, including the specific characteristics that are required for the group should be presented. Approaches should be outlined that will be used for the recruitment, retention, and follow-up of the required number of patients. Data should be presented supporting recruitment and retention estimates. Plans should be described for patient protection, including informed consent, monitoring of data for safety, and early termination as required. Appropriate informed consent forms from all participating groups (centers) should be included. Certification of approval from the Human Studies Committee (or its equivalent) for each participating institution should also be included. Projected rates of patient enrollment should be included. If enrollment falls behind projected levels, funding may be delayed or terminated.

The organization of the study and how the trial will be managed should be described, including the function of any internal or external advisory committees and any data and safety monitoring groups. In multicenter trials, you should provide a description of the responsibility and role of a data coordinating center, and policies and methods concerning blinding of study results. Accordingly, a plan should be submitted describing the procedure for the coordination of all participating centers. The Crohn's & Colitis Foundation does not assume responsibility for the conduct of the activities that the grant supports or the acts of the grant recipient as both are under the direction and control of the grantee institution and subject to the institution's medical and scientific policies. Grantee institutions must safeguard the rights and welfare of individuals who participate as subjects in research activities by reviewing proposed activities through an Institutional Review Board (IRB), as specified by the National Institutes of Health Office for Human Research Protections, US Department of Health and Human Services. These policies apply to applicants and applicant institutions as well. Finally, a timetable for completion of the various phases of the trial should be presented.

A procedure or plan for data management should be described, including data collection forms, if available. Data analysis methodology linking the analyses to the hypotheses to be tested should also be included. Primary and secondary end points should be clearly defined, justified, and related to the power calculations.

Evidential Enclosures:

Enclose letters of commitment from each participating center, signed by the cooperating investigator and business official. In addition, informed consent forms and evidence of Human Studies approval from all participating centers should be included in this section.

Curriculum Vitae:

Biographical sketches of all key investigators, center directors, and multidisciplinary team members should be included.

Facilities:

Clinical, data management, and laboratory facilities should be described in detail for all participating institutions, where applicable.

Budget:

A total overall budget and a complete justified budget for each year of support should be presented. If the trial is designed for more than the three-year period, complete justified budgets for the future years and a plan for securing funding for additional year(s) must be included. If the study involves multiple centers, a composite matrix should be submitted, where applicable. If parts of the costs of the total trial are to be provided by sources other than CCFA, these contributions should be presented in detail along with supporting letters from appropriate and responsible individuals. (Additional budget information will need to be submitted as attachment(s). These forms need to be completed and uploaded in the attachment section provided. The forms can be found in the form section of the CCFA web site.