



ACG CLINICAL RESEARCH AWARDS

2024 ESTABLISHED INVESTIGATOR BRIDGE FUNDING AWARD Request for Applications


This is a two-year award supporting 30% protected time as bridge funding for established investigators.

 **DEADLINE: MONDAY, DECEMBER 4, 2023, AT 11:59 PM EDT**

NOTE: Pre-Qualification Required before Submission. To Submit: bit.ly/33guW6k

 **APPLY: gi.org/research-awards**

 **Award Amount: \$300,000 / 2-YEAR AWARD (150K PER YEAR)**

 **Award period/length of award: July 1, 2024 - June 30, 2026**

The ACG Institute for Clinical Research and Education and the American College of Gastroenterology (ACG) are proud to support established clinical gastroenterology or hepatology researchers, who have experienced a lapse in federal program funding which requires bridge support to sustain their robust research programs, and invite eligible applicants to apply for a \$300,000, two-year bridge funding award, to be funded from July 1, 2024 - June 30, 2026. This award provides short-term bridge funding to sustain an investigator's independent research program between federal grants and is only available to ACG members.

All applications must be submitted online. The grant site will open to submissions on September 5, 2023, and close on Monday, December 4, 2023, at 11:59pm (Eastern time).

The goal of the Established Investigator Bridge Funding Award is to provide short-term (up to two-year) funding to established Clinical Scientists with a proven track record of federal program funding in innovative and impactful clinical research in gastroenterology or hepatology. With the paucity of federal agencies willing to fund GI and hepatology clinical research and federal funding levels at less than 15%, intermittent gaps in federal funding are a reality in the research career of an independent Clinical Investigator. This bridge funding grant is designed to support researchers principally focused on digestive or liver diseases, and to sustain their competitive, patient-oriented research programs during such a gap in federal program funding.

This grant is designed to support research that is principally focused on digestive or liver diseases. The patient population or disease target should be principally related to the gastrointestinal tract, liver, biliary system, pancreas, or neuroenteric science, including any translational, clinical, social science, or health services research studies that pertain to managing such patients or conditions. For example, a study about microbiota would be appropriate if it pertains to a digestive disease. In contrast, a study that is principally about HIV would likely not be appropriate unless it directly relates to how HIV affects digestive health. (For questions on study relevancy, contact the grant administrator at research@gi.org.) Since its inception in 1994, the ACG Institute for Clinical Research and Education has provided over \$29 Million in funding to over 721 recipients.



GRANT OVERVIEW

A key mission of the ACG and its Institute for Clinical Research and Education is to fund innovative patient-oriented research awards. For the purposes of these awards, patient-oriented research is defined as:

1. Research conducted with human subjects
2. Research on new diagnostic and therapeutic interventions
3. Research on material of human origin, such as tissues and specimens
4. Research that is translational in nature; i.e., has direct applicability to clinical care

Note: Studies involving animals will not be considered unless the work cannot be done in humans.



The ACG Clinical Research Awards are a project of the ACG Institute and are supported by charitable contributions to the ACG's ongoing fundraising campaign - The G.U.T. Fund.

✓ ACG Membership Requirement:

***Important!** The Principal Investigator must be an ACG member in good standing. Applicants awaiting final approval of their applications are ineligible. ACG membership must be active no later than October 2023. To Join ACG, [click here](#). For questions on ACG membership, please email membership@gi.org or call (301) 263-9000.

✓ Applicants must meet all the following criteria:

- ACG Member at time of application
- U.S. or Canadian based physician or equivalent (e.g., MD, DO, MBBS)
- Established Investigator definition:
 - A minimum of 8 years out of fellowship or terminal training program at time of application (fellowship or terminal training completed in 2015 or earlier to be eligible to apply for the 2024 grant cycle).
 - Evidence of successful federal funding.
 - Full-time faculty position as part of the gastroenterology or hepatology department at a university, medical school or other healthcare institution at time of application.
- Evidence of recently concluded federal clinical or translational research award within the last 3 years in gastroenterology or hepatology, such as NIH R01, K-award, or VA Merit Award. National Science Award, Department of Defense and CIHR multi-year project grant awards of equivalency [minimum direct costs of \$400,000/year] will be considered. Additionally, applicants must demonstrate one of the following:
 1. Evidence of ongoing application for renewal for federal funding (provide institutional evidence of application to a federal agency [i.e., eRA commons routing information] or letter of intent from institutional grant awards office)
 2. Evidence of new federal application (scored but not funded research grant) to be re-submitted (provide summary sheets and scores)
- Able to guarantee 30% protected research time for entirety of the grant period. Candidates must devote at least 30% of their effort to clinical research related to gastroenterology or hepatology. A letter from the Division Chief or Department Chair must certify that the award will provide 30% protected time to the recipient, regardless of the amount budgeted for salary, in accordance with the terms of the award.

✗ The following are not eligible for this award:

- Fellows-in-training.
- Early career faculty.
- Projects that support laboratory or animal research projects.
- Award overlap: ACG does not provide duplicate funding. The same science may not be used in applications for two ACG grant types (for example: applying to both the Bridge Funding Award and Clinical Research Award with the same science).
- ACG limits funding for a PI to one grant in a single award cycle. If a given investigator submits projects in two or more RFA categories and more than one is deemed worthy of funding, the larger grant will be funded.
- If the applicant was awarded an ACG research award within the last three (3) years, they cannot apply for the same grant category in which they were awarded. They may apply for a different grant category, as the College is not trying to limit progression of research (pilot award to CRA or JR Faculty Award), but rather the same investigators being funded repeatedly.



ELIGIBILITY



PREPARING THE RESEARCH PROPOSAL

A complete application consists of three separate components:

1. Submission of Required [Pre-Qualification Application](#) detailing the name of the grant, specific aims, brief research plan outline, current fundings status. This should be limited to 2 pages and submitted to the ACG before submission. Applicants will then be notified as to whether they should proceed with formal grant submission.
2. A single Adobe PDF document comprising (but not limited to) the following: application checklist (include the list located at the end of this document as the first page of the submitted PDF), research proposal (limited to 8 pages), budget, biosketches for Candidate and other Investigators involved in the proposed research, other support funding details, IRB forms, COI statement (if applicable), and letters of support.
3. Completion of required tasks via the online grant system: upload the completed research proposal PDF, which includes the application checklist; provide confirmation of ACG membership; provide full contact information for all Investigators submit a 350-word abstract of the proposed research; indicate IRB approval status; list all and any potential conflicts of interest. See “Submitting the Application” below for instructions and requirements.

Required elements for the full research proposal document (i.e., the PDF that will be uploaded to the online grant system):

- A. FORMATTING**—Format all pages with ½" margins and use a font no smaller than 11 point. All pages must include a page number in the left header. All pages must include the PI name and grant type in the right header, in the following format:
Last name, First name
Award Type
- B. CHECKLIST**—Include the Application Checklist listed at the end of this document, as the first page of the PDF uploaded to the grant system.
- C. ELIGIBILITY CONFIRMATION LETTER**—Letter Confirming you are eligible to apply for this award type. You will receive this letter after you submit the Pre-Qualifying Application.
- D. RE-SUBMISSIONS**—The Committee requires applicants who have applied previously to provide additional information when resubmitting the application. For re-submissions, in addition to selecting “Yes” in the resubmission field of the online system, you must provide a cover letter responding to the reviewer’s critiques/ outlining how you have updated your application. This should be included as the beginning of your Research Proposal, after the letter confirming your eligibility, as part of the PDF upload to the grant system. Limit to 2 pages.
- E. GLOSSARY OF TERMS (optional)**—Eliminate or minimize the use of abbreviations. Define each abbreviation the first time utilized, and/or provide a glossary of terms if needed to assist reviewers and strengthen your submission. Limit to 1 page.
- F. RESEARCH PROPOSAL**—Limit to 8 pages (excluding references). Outline the proposed research. In general, this should be a series of linked projects developed around a common theme, and should include the following sections:
 - **Specific Aims**—Provide a clear description of the study objectives. What is the hypothesis to be addressed? What are the immediate objectives? What are the ultimate objectives? How does the proposed research fit into an overall research program?
 - **Background/Significance**—State how the proposed work bears on prior work and indicate how it will extend the boundaries of current knowledge.
 - **Pilot Data/Previous Work**—This award type does not require pilot data. However, if the applicant has prior data pertinent to the present application, it should be briefly presented here. References to published work are preferred to detailed descriptions of published manuscripts.
 - **Research Plan**—Provide a detailed research plan, including the inclusion/exclusion criteria for enrollment, methods to be used, the kinds of data that are to be collected, and how these data will be analyzed. Provide detailed sample size estimates. Grants without a statistical analysis section or sample size justification are unlikely to be successful.
 - **Current Funding Status**—Indicate to which federal funding agency the initial grant application was submitted, and the outcome of this submission. Further indicate plans for re-submission. Also, address how the additional funding provided by this award will help address shortcomings in the initial research submission, as identified by the study section or review committee who assessed the initial grant.
- G. DESCRIPTION OF RESEARCH ENVIRONMENT**—Limit to 1 page. Describe the research environment, resources, and how this environment will provide enhanced support for the proposal. This section should describe how the research environment contributes to the success of the project and what type of institutional support, available equipment, and other additional resources will be accessible to the investigators. Additionally, elaborate as to how this specific environment is conducive to the project in terms of access to patients, samples, knowledge, or any collaborative arrangements (e.g., additional skills or referrals provided by collaborators). This section should help the reviewers understand the feasibility of completing this project.
- H. REFERENCES**—Include a separate section for references. Be judicious in the use of references.



PREPARING THE RESEARCH PROPOSAL (Cont.)

I. BUDGET AND JUSTIFICATION—Include a separate section for the budget and justification. Use the required [ACG budget format](#). The budget should indicate all expenses for the each year of the award. The budget justification should be listed on a separate page, after the budget template, with an explanation for each budget item (for example: justification for the number of hours supported by the grant, how statistical support will be utilized, etc.). Funding for this award will provide support of up to \$300,000 (150k per year) for research costs.

Allowable costs:

- Salary support for PI and Co-Investigators
- Salary support for other personnel (biostatistician, computer programmer, research coordinator, research nurse, etc.) if adequately justified.
- Labs, supplies, and equipment.

Costs not supported:

- Major equipment acquisition
- Manuscript preparation
- Travel
- Indirect costs (i.e., university overhead)

J. INSTITUTIONAL REVIEW BOARD (IRB) STATUS—Include the IRB approval letter, or indicate if IRB approval is pending. If IRB approval is pending at the time of submission and the grant proposal is subsequently approved for funding, funds will not be released until the IRB approval letter is received by the ACG. If the proposal is requesting funds for reimbursement of human subjects, a copy of the IRB-approved consent form is required prior to funding as well.

K. CONFLICT OF INTEREST STATEMENT—Include, if applicable.

L. BIOSKETCHES—Provide these for the Principal Investigator, Co-Investigator(s), and anyone critical to completion of the project. Use the NIH format and adhere to the NIH 5-page limit. (For sample format see the NIH webpage at grants.nih.gov/grants/forms/biosketch.htm)

M. INSTITUTIONAL REVIEW BOARD (IRB) STATUS—Include the IRB approval letter, or indicate if IRB approval is pending. If IRB approval is pending at the time of submission and the grant proposal is subsequently approved for funding, funds will not be released until the IRB approval letter is received by the ACG. If the proposal is requesting funds for reimbursement of human subjects or where the project studies care outside of standard of care a copy of the IRB-approved consent form is required prior to funding as well.

N. OTHER RESEARCH SUPPORT—List this information on separate pages. List the title, funding agency, total direct costs, dates, including expected dates of notification of pending applications for all current and pending funding for the Primary Investigator and Co-Investigators. (Use NIH format: grants.nih.gov/grants/forms/othersupport.htm). The Principal Investigator must include one of the following: 1) Evidence of ongoing application for renewal for federal funding (provide institutional evidence of application to federal agency) or 2) Evidence of new federal application (scored but not funded research grant) to be re-submitted. Provide summary sheets and scores.


O. INSTITUTIONAL SUPPORT—This letter from either the Division Chief or Department Chair should indicate strong commitment from the division to support the Candidate by protecting time for research and for providing adequate research facilities. The letter must certify that the award will provide 30% protected time to the recipient, reserved for the proposed research, in accordance with the terms of the award, regardless of the support budgeted in the application for the recipient's salary. Limit to 2 pages.

P. OTHER LETTERS OF SUPPORT (optional)—Provide letters from any other collaborators, such as those supplying patient referrals, if applicable. These may be included to demonstrate the other Investigators' involvement and support of the project (example: other research sites providing patients, or collaborator who will provide a unique set of skills required for the project).

Q. APPENDICES—Use (if needed) for data collection forms. Do not use to expand project description.



SUBMITTING THE APPLICATION

 **All applications must be submitted online.** The online grant application site will open September 5, 2023; a link to the site will be available at gi.org/research-awards. The submission **deadline is Monday, December 4, 2023, at 11:59 pm Eastern Time**. This deadline will be strictly enforced, and no exceptions will be made.

Note: Recommended [Pre-Qualification Application](#) due November 6, 2023.

Once you begin the online application process, you will be able to save your work and return to complete it until the submission deadline. As part of the online application process, applicants are required to provide information about others, such as institutional addresses and potential conflicts of interest for Co-investigators, etc. We encourage applicants to gather all the necessary information early and not wait until the last minute.



SUBMITTING THE APPLICATION (Cont.)

The following tasks must be completed via the online grant system to successfully submit an application for grant consideration:

- A. INDICATE PROPOSAL TITLE AND SELECT GRANT TYPE**—The title should be concise and clearly reflect the proposed research. Select the “Established Investigator Bridge Funding Award” grant type. (Please note, the same project should not be submitted for multiple ACG grant types, and will not be considered if this occurs, i.e., do not submit the same proposal for a Established Investigator Bridge Funding Award and a Clinical Research Award.)
- B. ACG MEMBERSHIP VERIFICATION**—You must provide your ACG member ID. To look up your member ID number, log into gi.org/membership then click “My ACG” from the menu on the top right. Member ID is listed below Date of Birth.
- C. ADD INVESTIGATORS**—List the Principal Investigator and any Co-Investigators. Enter their names, ACG member status (and year joined if available), titles, email address, role (Principal Investigator, Co-Investigator), and institution names and addresses.
- D. ACKNOWLEDGEMENT OF PRINCIPAL INVESTIGATOR**—Indicate agreement to abide by the grant requirements, if awarded grant funding.
- E. INVESTIGATOR ADDITIONAL INFORMATION**—Provide Principal Investigator’s academic position, and state whether the Principal Investigator has received federal clinical or translational research in gastroenterology or hepatology (within the last three years), such as NIH R01, K-award, or VA Merit Awards, National Science Awards, DoD or CCIHR multi-year project grant awards of equivalency [min. direct costs of \$400,000 /yr] will be considered.
Applicants must also demonstrate either: 1. Evidence of ongoing application for renewal for federal funding (provide institutional evidence of application to federal agency) or 2. Evidence of new federal application (scored but not funded research grant [i.e., eRA commons routing information] or letter of intent from institutional grant awards office) to be re-submitted (provide summary sheets and scores).
- F. RESEARCH PROPOSAL ABSTRACT**—Provide an abstract of no more than 350 words that summarizes the proposed research. In this section, you will also be asked to enter the topic area for your application.
- G. IRB STATUS**—Verify current IRB status.
- H. RESEARCH GRANT PROPOSAL PDF UPLOAD**—Format the file as required in the “Preparing the Research Proposal” section, including all required elements, and upload the file as directed. The file name should include the Candidate’s first and last name.
- I. CONFLICT OF INTEREST**—A potential conflict of interest (COI) exists when research involves a device from which any Investigator’s or a company may benefit. It also exists when research involves a pharmaceutical agent that is not FDA-approved for any indication. A conflict of interest exists if any Investigator holds or has submitted a patent on a device or pharmaceutical agent or is a major shareholder in a company involved in the research. If applicable, select “Yes” and include a detailed explanation within the grant system, including the names of each Investigator and their potential COIs.



APPLICATION REVIEW PROCESS

👁 **Immediately following the application submission period, all applications are reviewed and scored by the ACG Research Committee, following its standardized process.**

Reviewers consider the following when scoring applications: the feasibility, scientific and clinical significance of the research proposal, attributes of the Candidate (previous publication and funding record) and qualifications to perform high-quality research, and strength of the institutional environment, including a letter of support for 30% protected time if the proposal is funded.

In evaluating the merits of an application, the Committee will consider two categories of criteria, each comprising 50% of the overall assessment: 1) Project Merit, and 2) Individual Merit

1. Project Merit—50% of score includes:

- Scientific and clinical significance (12.5%)
- Feasibility (including availability of adequate resources, such as personnel and facilities) (12.5%)
- Methods (25%)
 - Availability of preliminary data (6.25%)
 - Study design (12.5%)
 - Power, sample size, and statistical analysis (6.25%)


2. Individual Merit (Credentials / Institutional Support / Previous record of funding success)—50% of score includes:

- Applicant’s Credentials
- Previous success in attracting and sustaining independent research funding
- Institutional Environment (including a letter from institution’s Division Chief / Department Chair supporting 30% protected time)

In general, the proposed research should be a series of linked projects developed around a common theme. The description of a proposed project should provide enough detail to assess the scientific merit, feasibility, and analytic strategy. An applicant may submit multiple applications if these applications each utilize different science and are submitted to different grant categories. Each applicant may only receive funding for a single submission each grant cycle. If more than one project is deemed worthy of funding, the larger grant will be funded.



AWARD NOTIFICATION AND GRANT REQUIREMENTS

 **Notification of Awards will be completed by April 1, 2024.** Please do not contact ACG prior to this date to inquire about the status of your application.

- **Funding:** Awards consist of \$150,000 per year for two years, for a total award of \$300,000. Funds are to be used for related expenses of the proposed research, including salary, supplies, and equipment. Funds are not to be used for: major equipment acquisition; travel and manuscript preparation; indirect costs (i.e., university overhead).
- **Clinical Research Leadership Program:** Award recipients have the option to attend the ACG Clinical Research Leadership Program in early 2024. No application is needed but confirmation of your plans to attend will be needed at the time of grant acceptance.
- **Required Progress Reports:** Awardees must file a progress report, on completion of the first year, for review by the ACG Institute Director and Research Chair, prior to the release of year two funding. This report must include proof of ongoing application for renewal of federal funding or new federal funding. A final report is due at the completion of the funding period must include an update on notice of award for subsequent funding. A final financial statement indicating allocation of funds is required. All reports must also be submitted to research@gi.org.
- **Abstract Presentation at an ACG Annual Scientific Meeting:** ACG encourages the selected Awardee to submit any abstracts to the ACG Annual Scientific Meeting for presentation.
- **Publication:** All publications arising from work funded by this award must acknowledge ACG support in any publications that result from the research.
- **Award overlap:** ACG does not provide duplicate funding. The aim of this award is to sustain the research until federal or other funding is obtained.



QUESTIONS OR ASSISTANCE

For any questions about grant requirements, please refer to the [FAQs](#).

Prior grant application submitters must create a new login for the grant system each year, even if you have applied for an ACG grant previously.

Technical support questions about the online submission system: Contact CadmiumCD Technical Support using the **Technical Support link on the upper right corner** of the submission site's screen, via email at Support@cadmiumcd.com or via phone at (877) 426-6323.

For any questions not answered in the RFA or [FAQs](#), or reporting questions, contact us via email at research@gi.org.



IMPORTANT DATES

September 5, 2023	Application submission period opens
September 15, 2023	ACG Membership application deadline (only for applications who are not ACG members—see the Eligibility Section for further details)
Monday, November 6, 2023	Recommended Pre-Qualification Application , submitted to ACG to check eligibility.
Monday, December 4, 2023	Application submission period closes (11:59 pm Eastern time)
By/before April 1, 2024	Award notifications are sent
July 1, 2024	Year 1 of award period begins / disbursement check provided
June 30, 2025	Year 1 progress report due (upon completion of first year) include any information on applications submitted for funding.
July 1, 2025	Year 2 of award period begins / disbursement check provided, once report approved.
June 30, 2026	Year 2 funding period complete
December 31, 2026	Final report and financial statement due (due earlier if only received one year of support)

✓ APPLICATION CHECKLIST: Established Investigator Bridge Funding Award

All grant applications must include this completed and signed Application Checklist as the **first page of the research proposal PDF that is uploaded to the grant system**. Submissions received without a signed and completed Application Checklist will be considered incomplete and will be disqualified. **Check each box to indicate completeness or check the box marked N/A for items not applicable for your submission. All boxes on the checklist must be reviewed and marked accordingly. Please sign this document before submitting.**

☑ Eligibility – double check full criteria, listed in eligibility section, prior to applying

You are a current ACG member. Confirm you are an ACG member in good standing prior to applying and you must have an ACG member number. Please note that this is different than applying for membership—all new member applications must be submitted by September 15, 2023.

Your ACG Member ID is _____.

You have completed the ACG Bridge Funding [Required Pre-Qualification Application](#) and have received a letter from ACG confirming eligibility. You are a U.S. or Canadian based physician or equivalent (e.g., MD, DO, MBBS)

You hold a faculty position as part of a gastroenterology or hepatology department at a university, medical school, or health care institution. You have completed fellowship more than eight years ago (fellowship or terminal training completed in 2015 or earlier to be eligible to apply for the 2024 grant cycle)

You have evidence of a recently concluded federal clinical or translational research award (within 3 years) in gastroenterology or hepatology, such as an NIH R01, or VA Merit Award. National Science Award, Department of Defense and CIHR multi-year project grant awards of equivalency [minimum direct costs of \$400,000/year] will be considered.

You demonstrate one of the following requirements:

- ☐ ☐ Evidence of ongoing application for renewal for federal funding
N/A (provide institutional evidence of application to federal agency [i.e., eRA commons routing information] or letter of intent from institutional grant awards office)
- ☐ ☐ Evidence of new federal application (scored but not funded research grant) to be re-submitted (provide summary sheets and scores)
You will have guaranteed 30% protected clinical research time for the entirety of the award period and have a letter from the Division Chief that certifies 30% protected time.
You are NOT a fellow-in-training.
You are NOT an early career faculty
Your submission does NOT involve animal research, unless the work cannot be done in humans.
The science for this award is NOT submitted for another ACG award category.
There will NOT be award overlap: ACG does not provide duplicate funding.

☑ Completion

You have created an account in the ACG grant system

(gi.org/research-awards)

You have a complete combined PDF, containing all necessary elements in the correct order, with this signed Application Checklist as the first page of the PDF to be uploaded to the grant system.

You have completed all necessary and relevant tasks required as part of the online grant system for this award application, including investigator information (ACG member number, title, email, role for project, institution, and address of institution); a 350-word abstract of the proposed research; listing research topics; a list of any potential conflicts of interest for investigators; indication of IRB approval status; re-submission status.

☑ Format of Submitted PDF

All pages must use 11-point font with minimum ½" margins.

The upper right header of each page must include your name and the award type, in the following format:

Last name, First Name

Award Type

The upper left header of each page must include the page number.

The sections of the PDF are numbered to match the Required Order of Submission as indicated on the checklist, with bold headers for each required section, and each bolded header section starts on its own page.

☑ Required Order of Submission

1. Application Checklist—This checklist is complete, signed by the Principal Investigator, and included as the first page of the submitted PDF.

2. Eligibility Confirmation Letter—You have completed the [Pre-Qualification Application](#), and have included the letter of eligibility confirming you are eligible for this award type as the second page of your application.

☐ ☐ **3. Glossary of Terms** (Optional)—The use of abbreviations and
N/A acronyms has been eliminated or minimized. A glossary of terms, if needed, has been added to assist reviewers and strengthen the submission.

☐ ☐ **4. Resubmission Response Letter**—If you are resubmitting this grant
N/A proposal, a 2-page (maximum) letter is included that responds to the reviewer's critiques and outlines how you have updated the application. Do not include this item if not applicable.

5. Research Proposal—Your research proposal project description should be a maximum of 8 pages (excluding references). It should include the following sections at a minimum: Specific Aims, Background/Significance, Pilot Data/Previous Work, Research Plan, and Current Funding Status.

6. Description of Research Environment—Describe the research environment, resources, equipment, and support and access to patients, samples, referrals, knowledge, or any collaborative arrangements which will support successful completion of this project. Limit to 1 page.

7. References—Include a list of all necessary and relevant references as well as citations in the project description.

8. Budget and Justification—Use the required [budget template](#) and include a separate budget justification after the budget table. The budget justification should include an explanation for each budget item, including facility fees if funds are requested for this purpose. By submitting the budget, you verify there will be adequate resources to complete the project.

9. IRB Status—An IRB approval letter or indication that IRB approval is pending is included. Informed consent documents must be provided where appropriate, such as projects where patient costs are reimbursed or if studying an intervention that is not part of routine care. If selected to receive the award, funds will not be released until ACG receives a copy of IRB approval.

10. Conflict of Interest Statement—Include a COI statement or indicate that none exist.

11. Biosketches—A biosketch for each investigator Principal Investigator, Co-Investigators) is included, all in the NIH format, maximum of 5 pages each. (grants.nih.gov/grants/forms/biosketch.htm).

12. Other Research Support—List the title, funding agency, total direct costs, dates, including expected dates of notification of pending applications for all current and pending funding for Principal Investigator, Co-Investigators. (Use NIH format: grants.nih.gov/grants/forms/othersupport.htm)

13. Institutional Support—The Division Chief or Department Chair must provide a 2-page (maximum), signed letter that certifies candidate has 30% protected clinical research time and support and adequate research facilities, regardless of the support budgeted for the recipient's salary. The letter also should indicate the requirements the institution has, with regards to applying for and receiving such funding, have been met.

☐ ☐ **14. Other Letters of Support** (Optional)—Included any optional letters
N/A of support that demonstrate involvement and support from additional Investigators (for example: other research sites providing patients; Specialists who will provide specialized training).

☐ ☐ **15. Appendices** (Optional)—use only if needed for data collection forms. Do
N/A NOT use to expand project description.

I certify that I have reviewed the Application Checklist and that all portions of my application are accurate and in the required order and format.

Signature of Principal Investigator

Date

Name (Printed)