Please note that you have to convert the document into a single PDF format that includes all your application documents in one document before submission.

Please put your documents in the same order as these directions:

ABSTRACT INSTRUCTIONS

2,000 characters max including characters and spaces

The abstract must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should contain a statement of objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate lay reader. Finally, please make every effort to be succinct. **This Summary must <u>not</u> include any proprietary/confidential information**.

INSTRUCTIONS FOR COMPLETING SPECIFIC AIMS

BE SURE TO PLACE YOUR NAME IN THE TOP LEFT CORNER OF THE PAGE!

State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.

List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

Applicants should be realistic in identifying the number of aims for their project. Two aims may be sufficient. There is no requirement that you must have three aims.

Specific Aims are limited to 1-page.

INSTRUCTIONS FOR COMPLETING THE RESEARCH STRATEGY SECTION

BE SURE TO PLACE YOUR NAME IN THE TOP LEFT CORNER OF EACH PAGE

PAGE LIMITS

AN APPLICATION MAY NOT BE CONSIDERED IF THIS SECTION FAILS TO OBSERVE THE PAGE LIMITATIONS.

- Career Development Grants: 12-page limit for Research Strategy and Educational Page
 - o AAFPRS Leslie Bernstein Investigator Development Grant
 - o AHNS/AAO-HSNF Young Investigators Combined Grant
 - AHNS/AAO-HNSF Translational Innovator Award
 - ARS New Investigator Award
 - o ASPO Research Career Development Award
- Research Grants: 6-page limit for Research Strategy
 - o AAFPRS Leslie Bernstein Resident Research Grant
 - AAFPRS Leslie Bernstein Grant
 - o AAFPRS Research Scholar Award
 - o AAO-HNSF Bobby R. Alford Endowed Research Grant
 - AAO-HNSF Health Services Research Grant
 - o AAO-HNSF Maureen Hannley Grant
 - AAO-HNSF Percy Memorial Research Award
 - AAO-HNSF Resident Research Award
 - AHNS Pilot Grant
 - o AHNS Ballantyne Resident Research Grant
 - AMD Resident Research Grant
 - ARS Resident Research Grant
 - ASPO Research Grant
 - Cook Medical/AAO-HNSF Resident Research Grant
 - o Xoran Technologies, LLC/AAO-HNSF Resident Research Grant

The Research Strategy section must contain three components: Significance, Innovation, and Approach.

Formatting:

Use an Arial, Garamond, Georgia, Helvetica, Palatino Linotype, Times New Roman or Verdana typeface, black font color, and a font size of 11 points or larger. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.)

Type density, including characters and spaces, must be no more than 15 characters per inch. Type may be no more than six lines per inch. Use standard paper size (8 $\frac{1}{2}$ " x 11). Use at least one-half inch margins (top, bottom, left, and right) for all pages. No information should appear in the margins.

Use the template provided to construct your research strategy. Include sufficient information in the research strategy to facilitate an effective review without reference to any previous application(s). Be specific and informative; do not assume that the reviewer will know what you mean. Reviewers often consider brevity and clarity in the presentation to be indicative of a

INSTRUCTIONS FOR COMPLETING THE RESEARCH STRATEGY SECTION

principal investigator/program director's focused approach to a research objective and ability to achieve the specific aims of the project.

Research Strategy

Organize the Research Strategy in the specified order and using the instructions provided below. Start each section with the appropriate section heading – Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography/References Cited.

Charts, tables, graphs, and photos essential to your application should be included in the body of your Research Strategy and will be counted in your page limits.

Supplementary or supportive charts, tables, graphs, and bibliography/references may be added in the Optional Appendix, however, the appendix should not be used to circumvent page limits.

(a) Significance

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services or preventative interventions that drive this field will be changed if the proposed aims are achieved.

(b) Innovation

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

(c) Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.

If an applicant has multiple Specific Aims, then the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively.

CAREER DEVELOPMENT GRANTS ONLY

INSTRUCTIONS FOR COMPLETING THE RESEARCH STRATEGY SECTION

In addition to the items identified above, career development applicants must include an educational plan (this is the reason for the 12-page limit versus 6-pages).

(d) Candidate's Background

Use this section to provide any additional information not described in the Biosketch, such as research and/or clinical training experience.

(e) Career Goals and Objectives

Describe your past scientific history, indicating how the award fits into past and future research career development. If there are consistent themes or issues that have guided previous work, these should be made clear; if your work has changed direction, the reasons for the change should be indicated. It is important to justify the award and how it will enable you to develop or expand your research career. You may include a timeline, including plans to apply for subsequent grant support.

(f) Career Development/Training Activities During Award Period

Stress the new enhanced research skills and knowledge you will acquire as a result of the proposed award. If you have considerable research experience in the same areas as the proposed research, reviewers may determine that the application lacks potential to enhance your research career. For mentored awards, describe structured activities, such as course work or technique workshops, which are part of the developmental plan. If course work is included, provide course numbers and descriptive titles. Briefly discuss each of the activities, except research, in which you expect to participate. Include a percentage of time involvement for each activity by year, and explain how the activity is related to the proposed research and the career development plan.

(g) Training in the Responsible Conduct of Research

For mentored career development awards, describe a plan to acquire instruction in the responsible conduct of research. For independent career awards, describe a plan to obtain or provide instruction in the responsible conduct of research.

Include a description of plans for obtaining instruction in the responsible conduct of research. This section should document prior instruction or participation in RCR training during the applicant's current career stage (including the date instruction was last complete) and propose plans to either receive instruction or participate as a course lecturer, etc., in order to meet the once every four-year requirement. The plan may include career stage-appropriate individualized instruction or independent scholarly activities that will enhance the applicant's understanding of ethical issues related to their specific research activities and the societal impact of that research. The role of the mentor in RCR instruction must be described.

INSTRUCTIONS FOR COMPLETING RESOURCES AND ENVIRONMENT

BE SURE TO PLACE YOUR NAME AT THE TOP LEFT OF EACH PAGE!

Follow the instructions on the form. When pertinent, the clinical population available at the institution may be listed under "Clinical."

INSTRUCTIONS FOR COMPLETING BUDGET AND BUDGET JUSTIFICATION

BE SURE TO PLACE YOUR NAME IN THE TOP LEFT CORNER OF EACH PAGE!

FORM: DETAILED BUDGET FOR 12-24-MONTH PERIOD DEPENDING ON THE GRANT MECHANISM FOR WHICH YOU APPLIED:

Personnel: Whether or not salaries are requested, list the names and roles of all applicant organization personnel involved in the project during the first 12-month budget period. Then complete the form for the second 12-month period if applicable. Starting with the PI, list all key personnel, and then support personnel. **Key personnel** are those individuals who participate in the scientific development/execution of the project. This will generally include individuals with professional degrees, but may also include individuals with other degrees at the masters and baccalaureate levels. **Support personnel** are those individuals who provide administrative or technical assistance to the project, e.g., dishwashers, animal caretakers, histopathology technicians, electron microscopy technicians, and in some instances research technicians or associates.

Role on Project: Identify the role of each individual listed on the project. Describe their specific functions. Provide budget narrative for ALL personnel by position, role, and level of effort using person months (calendar, academic, and/or summer.

Months Devoted to Project. Enter the number of months devoted to the project. Three columns are provided depending on the type of appointment being reflected: academic, calendar, and/or summer months. Individuals may have consecutive appointments within a calendar year, for example for an academic period and a summer period. In this case, each appointment should be identified separately using the corresponding column.

If effort does not change throughout the year, use only the calendar months column. If effort varies between academic and summer months, leave the calendar months column blank and use only the academic and summer months columns. In cases where no contractual appointment exists with the applicant organization and salary is requested, enter the number of months for the requested period. Some measurable effort is required for every Senior/Key Person entry.

Effort: Effort must be reported in person months. For help converting percent effort to person months, see: http://grants.nih.gov/grants/policy/person_months_fags.htm.

CALCULATING PERSON MONTHS

What is the definition of person months?

Person months - Is the metric for expressing the effort (amount of time) PI(s), faculty and other senior personnel devote to a specific project. The effort is based on the type of appointment of the individual with the organization; e.g., calendar year (CY), academic year (AY), and/or summer term (SM); and the organization's definition of such. For instance, some institutions define the academic year as a 9-month appointment while others define it as a 10-month appointment.

How do you convert percent effort into Person Months?

Conversion of percentage of effort to person months is straight-forward. To calculate person months, multiply the percentage of your effort associated with the project multiplied by the number of months of your appointment. For example:

25% of a 9 month academic year appointment equals 2.25 (AY) person months (9 x 0.25= 2.25)

10% of a 12 month calendar appointment equals 1.2 (CY) person months (12 x 0.10 = 1.2)

35% of a 3 month summer term appointment equals 1.05 (SM) person months (3 x 0.35= 1.05)

10% of a 0.5 FTE 12 month appointment equals 0.6 (CY) person months $(12 \times 0.5 \times 0.1 = 0.6)$

Another example:

If the regular pay schedule of an institution is a 9 month academic year and the PI will devote 9 months at 30% time/effort and 3 months summer term at 30% time/effort to the project, then 2.7 academic months and .9 summer months should be listed in the academic and summer term blocks of the application (9 x 30% = 2.7 person months; $3 \times 30\% = .9$)

Effort Conversion Table NIH Effort Conversion Calculation Chart worksheet

***Please refer to the individual funding opportunity announcement to determine allowable salary support. ***

See examples 1 and 2 on the <u>NIH Effort Conversion Calculation Chart worksheet</u> for help on calculating salary requests.

Base salary is defined as the compensation that the applicant organization pays for the individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of duties to the applicant organization. Base salary may not be increased as a result of replacing institutional salary funds with grant funds. Fringe benefits may be requested, provided such costs are treated consistently by the applicant organization as a direct cost to all sponsors.

Enter the dollar amounts for each position for which funds are requested. If a lesser amount is requested for any position, explain on page 3 (e.g., endowed position, institutional sources, other support). Enter on the appropriate separate lines the salaries requested for the year.

Calculate the totals for each position and enter the subtotals in each column where indicated.

Consultant Costs: Whether or not costs are involved, provide the names and organizational affiliations of any consultants, other than those involved in consortium/contractual arrangements, who have agreed to serve in that capacity. Include consultant physicians in connection with patient care. Briefly describe and justify on page 3 the services to be performed, including the number of days of consultation, the expected rate of compensation, travel, per diem, and other related costs.

Please note that consultants do not have an ongoing, day-to-day role in the project (e.g., performing molecular biology tests, performing auditory assessments, etc.), but rather provide advice and expert opinion about details of the project and its progress on the occasional basis. Those who play specific, expert roles in the procedure should be named as coinvestigators, and their time commitments and salary support (if any) defined according to the guidelines above.

Equipment: List separately each item of equipment. If funds are requested to purchase items of equipment that appear to duplicate or to be equivalent to items listed on the Resources and Environment page or items used in preliminary studies, justify the reasons for the duplication on page 3. Requests for computer equipment should be justified with particular care; convenience and availability are not considered to be strong justifications. All equipment purchased under the terms of this Award become the property of the host institution and may not be removed by the principal investigator without specific release by the institution.

Supplies: Itemize supplies in separate categories such as glassware, chemicals, radioisotopes, etc. Categories in amounts less than \$500 do not have to be itemized; however, if animals are involved, state how many are to be used, their unit purchase cost, and their unit care cost. Incentive payments, reimbursement of travel expenses, etc. for human subjects should be listed in this category.

Travel: In general, funds are not to be requested for travel unless it is essential to the conduct of the proposed project; such requests should be fully justified and explained on page 3. **Please refer to individual funding opportunity announcement for reference.**

Patient Care Costs: If inpatient and/or outpatient costs are requested for research with human subjects, provide the names of the hospitals or clinics to be used and the amounts requested for each on page 3. State whether each hospital or clinic has a currently effective DHHS-negotiated research patient care rate agreement, and if not, what basis is used for calculating costs. Indicate in detail the basis for estimating costs in this category, including the number of patient days, estimated cost per day, and cost per test or treatment. Expenses for reasonable and ordinary diagnostic or treatment procedures that would be routinely undertaken for the condition under study, and for which reimbursement is available, may not be charged to the grant. Patient care costs do not include travel, lodging, and subsistence or incentive fees; such fees, if necessary, should be listed under Supplies.

Alterations and Renovations: Itemize by category and justify on form page 3 the costs of alterations and renovations (including repairs; painting; removal or installation of partitions, shielding or air conditioning).

Other Expenses: Itemize by category and unit cost such other expenses as publication costs, page charges, books, computer charges, microscopy charges, rentals and leases, equipment maintenance, minor fee-for-service contracts, etc. Justify cost on page 3.

Indirect Costs: The societies prefer not to pay any institutional (indirect) costs for these very modest awards; if the institution is unwilling to waive such costs, however, they are limited to no more than 10% of the Total Direct Costs (sum of amounts requested for personnel, consultant costs, equipment, supplies, travel, patient care costs, and other expenses).

All items appearing on the budget page should be fully justified, including the use of key and support **personnel**. This is especially important in the case of equipment, unusual patient/subject costs, travel, other expenses, etc. Whenever possible, vendor estimates or quotes on requested equipment should be attached to the application.

For additional years of support (more than one year):

Enter the totals under each budget category for each additional year of support requested. Identify with an asterisk and justify any significant increases or decreases from the initial budget year.

SEE PAGE NEXT FOR SAMPLE BUDGET JUSTIFICATION. This includes only the detail for the budget justification section of the form.

References

https://grants.nih.gov/grants/funding/phs398/phs398.pdf https://nexus.od.nih.gov/all/2015/05/27/how-do-you-convert-percent-effort-into-person-months/ http://grants.nih.gov/grants/policy/person_months_faqs.htm#1040 https://medschool.duke.edu/research/research-support-offices/office-research-administration/awardmanagement/effort-management https://bcmp.med.harvard.edu/sites/bcmp.med.harvard.edu/files/administration/BUDGET%20JUSTIFICATION %20template.pdf

Example Detailed NIH

SAMPLE BUDGET JUSTIFICATION (Slightly modified)

PERSONNEL

<u>Jane Doe, Ph.D., Principal Investigator</u> (effort = 2.5 calendar months). Dr. Doe will be responsible for the overall coordination and supervision of all aspects of the study. This includes hiring, training, and supervising staff/students; recruiting study participants; coordinating treatment and assessment components; scheduling and staff assignments; and data management. In addition, she will conduct the orientation sessions, assist with statistical analyses, and be responsible for reporting the study's findings.

<u>Suzan Raines, Ph.D., Co-Investigator</u> (effort = 0.8 Academic Months, 1.0 Summer Months). Dr. Raines will be responsible for the collection and analyses of the fecal materials. She will also assist in manuscript preparation.

OTHER PERSONNEL

<u>TBA Post Doctoral Associate</u> (effort = 12 Calendar Months effort). This individual will coordinate the day-today management of the study, assist in assessments, be responsible for data entry of all treatment-related data (i.e., scheduling and conducting weights, attendance, self-monitoring), and serve as an interventionist.

<u>TBA Project Coordinator</u> effort = (6.0 Calendar Months). This individual will assist with recruitment, assessments, and serve as an interventionist. Additionally this person will aid with preliminary data analyses and manuscript preparation. It is anticipated that this individual would start with 1-year of previous experience.

<u>TBA Research Assistant</u> (effort = 12 Calendar Months). This individual will assist with recruitment, ordering supplies and intervention materials, assessments, collection of dietary data, daily management of study data, and scoring and data entry of assessments.

EQUIPMENT

Funds are requested to purchase three Biologs (\$7,150 each). These are ambulatory physiological data recorders with multiple channels that will be used to record mothers' heart rate (RSA), activity level, and electrodermal activity (e.g., skin conductance). Recorded data is compactly stored on a removable memory card. When recording is complete, the card is inserted into a card reader which is connected to a PC through a serial port. The affiliated Downloading and Plotting Software (\$1,100 under supplies) which operates on the PC supervises the downloading of data to the PC and ensures data is recorded according to the needs specified by the researchers. From this program, the data can be converted into separate data files for each physiological measure. These measures are all synchronized with one another and can be synchronized with video files as well. Three Biologs are needed because there are several periods when assessment points overlap (e.g., parental interviews, 6 months laboratory visits, 6 months home visits), and dedicated equipment for each type of visit will ease scheduling demands.

<u>TRAVEL</u> - \$2500 in Year 01 is requested for travel to professional conferences (e.g., CDC, SRA) to present findings associated with the investigation.

PATIENT CARE COSTS

None

ALTERATIONS/RENOVATIONS

None

OTHER EXPENSES

F.1 Materials and Supplies

General research supplies - Research supplies are calculated at approximately \$30,000 per year, and include blank DVD's for data storage as well as all testing materials.

F. 3. Consultants

In Years 1 and 2, Dr, Carol Adams from the University of Northern Virginia will train 3 research assistants to administer the Adult Attachment Interview (AAI). She will periodically review interview transcripts to ensure adherence to the interview protocol over time. Dr. Adams will assist in identifying trained AAI coders. She will provide support for this project at a rate of \$400 per day for 5 days during the Years 1 and 2

FACILITIES AND ADMINISTRATIVE COSTS (INDIRECT COSTS)

BE SURE TO PLACE YOUR NAME AT THE TOP LEFT OF EACH PAGE!

NIH and AHRQ has a new biosketch format that went into effect for research applications submitted after May 25, 2015. (Notification Information: <u>http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-024.html</u>)

Instructions for 2018 Endocrine Section Pilot Grant applicants:

Include biosketches for all key personnel, including co-investigators, and consultants.

The biosketch should include the following sections:

- A. Personal Statement
- B. Positions and Honors
- C. Contributions to Science <u>OR</u> a list of relevant publications
- D. Research Support
- Do not exceed 5 pages per individual.

Key changes to the biosketch include:

- Extending the biosketch page limit from four pages to five pages
- Allowing researchers to include up to four references in their personal statement
- MODIFICATION: Researchers must complete the Contributions to Science section per NIH guidelines <u>OR</u> provide a list of relevant publications. If completing the Contributions to Science, researchers may describe up to five of their most important contributions to science
- Allowing researchers to include a link that provides access to a full list of their published work (peer-reviewed, non-peer reviewed and accepted for publication)

Requirements of the new NIH biosketch are included on the following pages.

BE SURE TO PLACE YOUR NAME AT THE TOP LEFT OF EACH PAGE!

The biosketch format includes four major sections.

- A. Personal Statement
 - May now include up to four *peer-reviewed* publications that specifically highlight your experience and qualifications for the project
 - <u>May</u> include a description of factors e.g. family care responsibilities, illness, disability, active duty military service to explain impediments to past productivity
- B. Position and Honors (unchanged from previous biosketch form)
- C. Contributions to Science (new) New required section that may optionally include references and a link to your complete bibliography. Alternatively, you may provide a list of relevant publications in this section. You are required to provide one of these options. <u>Please Note</u>: Providing a list of relevant publications in lieu of the Contributions to Science will not negatively affect your application.
 - IF YOU ARE OPTING TO COMPLETE THE CONTRIBUTIONS TO SCIENCE SECTION, PLEASE USE THE FOLLOWING GUIDELINES:
 - 1. Include up to five contributions to science
 - 2. Include **up to four references for each contribution**; see Details below for the types of content that can be cited in this new section
 - 3. Link to a full list of your published work as found in a publicly available digital database; NCBI's My Bibliography is recommended.
 - i. Including this link is currently optional
 - <u>No other links/URLs</u> may be allowed in the biosketch or application
 - The online bibliography link/URL may be either active (clickable) or not active
 - Whether active or inactive, the link/URL to the online bibliography must be spelled out (http:// etc) and cannot be hyperlinked text/words.
 - This online bibliography link and the up to 24 references included in the Personal Statement and Contributions to Science sections

BE SURE TO PLACE YOUR NAME AT THE TOP LEFT OF EACH PAGE!

replace the previous 15 reference bibliography used in the old biosketch.

D. Research Support (unchanged from previous biosketch template)

Details on New Components

1. Section C Contributions to Science (IF PROVIDING)

- Briefly describe up to five of your most significant contributions to science. Be sure to include:
 - the historical background that frames the scientific problem
 - the central finding(s)
 - the influence of the finding(s) on the progress of science or its application to health and technology
 - your specific role in the described work
- Each contribution can reference up to four peer-reviewed publications OR other nonpublication research products including audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware.
- The description of each contribution must be no longer than one half page including citations and figures.

2. URL to Complete List of Published Work (component of Contributions to Science section)

- Start putting together your online bibliography as soon as possible. My Bibliography (in <u>My NCBI</u>) is the tool that NIH recommends:
 - My Bibliography in your <u>Mv NCBI</u> account: Use the <u>sharing feature</u> to create a
 public link to your works that you can add to your biosketch (created using either the
 online SciENcv tool or the NIH Word template).
 - Alternatives to My Bibliography? (From <u>NIH Biosketch FAQ #4</u>):

"Per <u>NOT-OD-15-032</u>, the new biosketch format allows applicants to include a link to a full list of their published work as found in a "publicly available digital database" such as My Bibliography. The link is optional.

BE SURE TO PLACE YOUR NAME AT THE TOP LEFT OF EACH PAGE!

NIH cautions reviewers against accessing URLs that may compromise their anonymity. The NIH prefers applicants use My Bibliography because the NIH can assure reviewers that their anonymity will be protected if they review publications at that site. Use of a publicly available database other than My Bibliography is at the discretion of the applicant, but applicants should bear in mind that reviewers are unlikely to click on unknown links. These links must be accessible to the general public without registration and must not point to informational websites that may violate page limit rules (NOT-OD-11-080).

For these reasons, linking to a lab or researcher's site would be inappropriate."

- URL Construction (if inserting the link into Word template; My NCBI handles URL construction automatically)
 - Spell the URL out in full, beginning with 'http://' (e.g., http://grants.nih.gov/grants/oer.htm).
 - Do NOT include the link as hyperlinked text (e.g.,<u>NIH Grants Web page</u>) as eRA system processing will not retain the active link in the assembled application image in eRA Commons.
 - The online bibliography link/URL may be either active (clickable) or not active

New Biosketch Creation Tools

 <u>SciENcv</u>: This is a new online tool that is designed to create biosketches for NIH grant applications. This tool eliminates the need to repeatedly enter biosketch information. SciENcv will output a biosketch in Word, PDF or XML formats.NOTE: It is recommended that you set up your My Bibliography first.

INSTRUCTIONS FOR COMPLETING OTHER SUPPORT PAGES

BE SURE TO PLACE YOUR NAME IN THE TOP LEFT CORNER OF EACH PAGE! Other support also includes all financial resources, active and pending. Include a section for each of the key personnel, even if they have no currently active support.

NOTE: Applicants must clearly indicate in this section of the application whether support for the submitted project is being sought from other funding agencies or organizations.

CO-INVESTIGATOR, PRECEPTOR, MENTOR, CONSULTANT, COLLABORATOR LETTERS

If a co-investigator, preceptor, or mentor will play a key role in the project, a letter of understanding from that individual must be submitted, stating what the arrangement will be and what role s/he will play in the project. Also include an appropriate letter from each consultant and collaborator confirming his/her role in the project. Include Biographical Sketch pages for each consultant and collaborator.

In general, if an individual's biosketch is included in your application, plan to obtain a letter from that person.

Instructions for scanning and uploading letters.

The signed letters must be scanned at 100%, and at least 150 dots per inch resolution.

DEPARTMENT/CHAIR HEAD LETTER

A Chairman's letter must be included with all applications. Applications **must** include a letter of reference and support from the applicant's Chairman confirming the applicant's availability for the required period of time, the support of the Department or Division for the project, and availability of resources for the project. For residents, the Chairman's letter must verify that the resident applicant will be permitted to spend the specified time on the project.

Instructions for scanning and uploading letters.

The signed Department/Chair Head Letter must be scanned at 100%, and at least 150 dots per inch resolution.

PRECEPTOR/MENTOR LETTER - INSTRUCTIONS

The applicant is responsible for selecting a research preceptor at an academic or nonprofit research institution and for making arrangements to work with that person. The designated preceptor must be the faculty member who will directly supervise the proposed research training and evaluate the awardee's progress. An applicant may have a co-preceptor if his/her research interests cross areas of expertise. Selection of a preceptor is a key step in the application process and will constitute an important review criterion. In general, the applicant should seek a successful clinical researcher who has recent publications in the area of research, experience in the research techniques to be studied, and, optimally, external grant support from NIH or other major agencies. Location in a department that will provide a stimulating and supportive research environment is an additional factor to consider. The applicant's preceptor should be an active investigator in the area of the proposed research who will directly supervise the candidate's research. The preceptor must document the availability of staff, research support, and the curriculum and facilities for high-quality clinical research training. The proposed training shall be designed in collaboration with the designated mentor and approved by the applicant's Department/Division Chair and institution. Training should be specifically focused on the acquisition and refinement of patient-oriented clinical research skills and may include both didactic course work and applied experience. A structured program of study (as opposed to informal directed readings) will be reviewed most favorably. Applications must be accompanied by letters of support from both the applicant's preceptor and from the Department/Division Chair, verifying that the applicant will be permitted to devote the specified amount of time to the proposed research and research training activities.

Mentor requirements for the Endocrine Section Pilot Grant:

Applications must be accompanied by a letter of support from the applicant's mentor, outlining the mentor's commitment to the candidate and willingness to engage in research updates and critical review of the candidate's progress on a monthly basis at minimum. Ideally the mentor should be at the same institution, however, it is possible that they could be elsewhere as long as they will work with the recipient in meeting the goals of the grant. The mentor will serve to advise the candidate on both scientific and career issues and is his/her advocate at the institutional level. The mentor, in conjunction with the department/institution, is expected to ensure that the awardee has the protected time and the resources to complete the research project and career development plans as outlined in the funded application. The mentor may not be funded directly by the grant. He/she should be someone who will work with the recipient on their project, providing guidance and support.

INSTRUCTIONS FOR OPTIONAL APPENDIX

The appendix must not be used to circumvent page limits. Graphs, diagrams, tables, and charts that are supplementary or supportive of the application may be submitted as appendix material. However, keep such material to a minimum; <u>tables and graphs essential</u> to the application must be included within the 6 or 12-page limit of the Research Strategy. You may include your references/bibliography in the appendix.

INSTRUCTIONS FOR IRB/IACUC DOCUMENTATION

Include any IRB or IACUC documentation for your application here. It is to the applicant's benefit to include institutional endorsements with the application. If such endorsements are pending when the application is submitted, include all of the documentation that was submitted to your review board so reviewers can see that the IRB/IACUC approval is in process.

Once the final approval is received, email the pdf to Betty Mulugeta betty@ahns.info

Endorsements should specifically cite the applicant's name and project title.

If you do not have your IRB or IACUC approval prior to the application deadline, you may email it to Betty Mulugeta betty@ahns.info

A resubmission is an application that has been previously submitted and reviewed. In the event that a different PI submitted the previous application, it is not appropriate to resubmit an application without acknowledging the previous PI. Include a brief letter of permission from the previous PI with your letter.

1. If you are resubmitting an application. You are required to include a letter, a copy of your critique, or the previous PI's critique, and if applicable, a brief letter of permission from the previous PI.

2. The letter to the Study Section should outline what has been modified in the application based on the critique and if applicable, acknowledging the previous PI's submission.

Please email the letter to: betty@ahns.info

3. Your cover letter, critique, and permission letter (if applicable), must be in one file and included as the Summary Statement (Resubmissions Only) attachment in your proposal.

4. Be sure the Research Strategy is in the correct format (6 or 12 pages depending on the grant mechanism) for which you are applying.

Please note that you have convert the document into a single PDF format that includes all your application documents in one document before submission.