

ALPHA-1 RESEARCH GRANT (A1)

The Alpha-1 Foundation and the American Lung Association Alpha-1 Research Grant Description, Award Terms and Conditions and Application Guide

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Applicants are strongly advised to read completely through the program description, award terms and conditions and application guide before starting an application.

About the American Lung Association Awards and Grants Program

Research is crucial to a future where lung disease no longer threatens the health of our families and friends. To help Americans live longer, healthier lives, we must find better methods of detection, treatment and cures for all lung diseases. For over 100 years, the American Lung Association has supported research to achieve this goal and we continue to fund, develop, promote and advocate for research and programs that will result in life-changing advances for people impacted by lung disease. The goal of the American Lung Association Awards and Grants Program is to fund researchers at important crossroads of their careers, gaining a long-term commitment to lung disease research.

About the Funding Opportunity

To encourage research on advancing the understanding of Alpha-1 Antitrypsin Deficiency, the American Lung Association has teamed up with the Alpha-1 Foundation to offer the Alpha-1 Research Grant. The objective of the Alpha-1 Research Grant is to support clinical, laboratory, epidemiological or any other kind of research projects aimed at developing novel medical treatments, advancing current treatment options or finding a cure for Alpha-1 Deficiency.

The Alpha-1 Research Grant is for **\$40,000 per year for up to two years**. No more than 75% of the requested budget may be used for an awardee's salary and/or fringe benefits and no more than 30% of the total award budget may be used to fund the purchase of permanent equipment. Grant funds may be used for the salary and fringe benefit costs of personnel other than the Applicant.

All awards are subject to availability of funds on the start date. Grants are subjected to annual review and may be granted for two years. The second year of support is based on demonstrating satisfactory progress, as well as, the availability of funding from the Lung Association and the Alpha-1 Foundation. While the awards will be administered by the Lung Association, award recipients will be selected and funded equally by both organizations.

Key Dates

August 23, 2016	Applications accepted through proposalCENTRAL
December 15, 2016	Deadline to submit an application is Thursday, December 15, 2016 (11:59 PM, Eastern Time)
February- April	Peer Review Period
June 2017	Funding notifications are sent to all applicants

Important Notes

Applicants are limited to submitting only one application per annual cycle. Applicants found ineligible or noncompliant with these guidelines will be administratively withdrawn. Applicants are encouraged to retain a copy of this document for future reference.

It is recommended that applicants submit projects to the appropriate Institutional Animal Care and Use of Committee (IACUC) and human subjects Institutional Review Board (IRB) at the time of application or before. Copies of the approvals must be provided to the American Lung Association prior to the start of an award; otherwise the award may be administratively withdrawn.

Eligibility Requirements

Citizenship

At the time of application, candidates must be United States citizens or foreign nationals holding one of the following visa immigration statuses: permanent resident (**Green Card**), exchange visitor (**J-1**), temporary worker in a specialty occupation (**H-1B**), Canadian or Mexican citizen engaging in professional activities (**TN**), Australians in Specialty Occupation (**E-3**) or temporary worker with extraordinary abilities in the sciences (**O-1**). At the time of application and throughout the award, an applicant must be employed by a U.S. institution.

Mentor Requirement

Applicants should be on-track to pursue a career in lung disease research with a mentor who has a demonstrated history of research experience and mentorship.

Education and Experience

At the time of application, the applicant must hold a doctoral degree and have a faculty appointment or equivalent with demonstrated institutional commitment (salary support, research space) in a recognized academic or other not-for-profit institution. *Fellows and PhD post-docs are eligible to apply only if their Department Chair can assure a promotion to faculty status by the start of the award.* MD applicants must have completed two years of post-doctoral research training by the start of the award.

Medical residents, those presently enrolled in a degree program (e.g., graduate students), and established investigators are not eligible to apply. Factors that are considered indicative of an established investigator include, but are not limited to, academic rank of professor or associate professor; awards of established investigatorship (e.g., NIH-R01 Awards, Veterans Administration Merit Review Awards), an extensive bibliography, or a national reputation as an investigator in their field.

Peer Review

Applications deemed eligible for funding will go through a rigorous external peer review process. Factors considered when reviewing applications include:

- Scientific merit, technical feasibility, innovation and project relevance to the mission of the American Lung Association and the Alpha-1 Foundation.
- Applicant's education, experience and recommendation letters
- Research environment and mentorship plan
- Likelihood that the applicant will engage in an ongoing career in lung health research
- Department Chair (or equivalent) letter clearly assuring faculty appointment with demonstrated institutional commitment before the start of an award

Award Terms and Conditions

Animal Use

The American Lung Association allows animal use in biomedical research only when no other means of obtaining scientifically sound, valid and useful results are available. Applicants/ awardees must comply with the Public Health Service Policy on *Human Care and Use of Laboratory Animals* and the National Research Council *Guide for the Care and Use of Laboratory Animals* to the same extent as each would were the research funded by the National Institutes of Health. A copy of the Institutional Animal Care and Use of Committee (IACUC) approval and/or the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) accreditation must be provided to the Lung Association before the start of an award; otherwise the award may be administratively

withdrawn. Applicants from institutions that do not have accreditation from the AAALAC, USDA and/or IACUC are not eligible to apply.

Authorized Award Holders

Awards are granted on behalf of specific individuals. Awards cannot be transferred to another individual. If a grantee cannot complete the research, the funds will revert back to the American Lung Association and the Alpha-1 Foundation.

Award Allocation

Biomedical Research Grants are for \$40,000 per year. No more than 75% of the requested budget may be used for an awardee's salary and/or fringe benefits and no more than 30% of the total award budget may go to fund the purchase of permanent equipment.

Award Payments

Award payments are issued by the American Lung Association twice a year - July and January.

Biohazards

Biohazards are broadly defined to be recombinant and/or infectious and tumor materials that may be deleterious to normal organisms upon controlled exposure. Research involving biohazards requires a copy of the appropriate institutional committee approval to be sent to the American Lung Association before the start of an award; otherwise the award may be administratively withdrawn.

Carry Over and No Cost Extensions

Requests for carry over or award extensions require prior approval by the American Lung Association and the Alpha-1 Foundation. *All requests must be in writing and sent to Research@lung.org.* The written requests for carry over and/or extensions must be received by the American Lung Association thirty days prior to the award's official termination date. When requesting a carry over, the awardee must indicate: the amount, from what budget line and to what budget-line the monies are being applied. In the case of supply or equipment budget, all items must be itemized. *Awardees can only request a carry over and/or extension once per award.*

Change of Budget

Requests for changes in budget require prior approval by the American Lung Association. *All requests must be in writing and sent to Research@lung.org.* When requesting a change in budget, the awardee must indicate: the amount, from what budget line and to what budget-line the monies are being transferred. In the case of supply or equipment budget, all items must be itemized.

Change of PI Status or Award Transfer

The intention of these awards is to support career development for early career investigators. Although transfers may be allowed, transfer of an award from one institution to another requires prior approval by the American Lung Association, approvals are granted on a case by case basis. *A transfer application may be requested by emailing research@lung.org.* All unexpended funds must be returned to the American Lung Association within 45 days of transfer approval. Once the Lung Association approves the transfer and receives the unexpended funds, the remaining funds will be reissued to the new institution.

Correspondence and Communications

The American Lung Association corresponds directly with all awardees. As such, it is the responsibility of the awardee to ensure institutional personnel are copied on all American Lung Association correspondence. Award recipients are expected to collaborate with the Lung Association's marketing and communications team to share the relevance of their project with our constituents.

Discretionary Funds

No more than \$2,500 per annum may be used for travel; publications; supplies or other expenses directly related to the American Lung Association- funded project and within the award terms and conditions.

Equal Employment Opportunity

The American Lung Association will only award individuals working in institutions identified as Equal Opportunity Employers.

Equipment Expenditures

No more than 30% of the total award budget may be used to fund the purchase of permanent equipment. Equipment is defined as an item that costs \$500 or more, has a primary function related to the research project, and ordinarily has a usable life expectancy of one year or greater.

Equipment and Supply Purchases

Upon conclusion of the award, equipment and supplies purchased with funds from the award become the property of the institution at which the work was done. Any departure from this clause requires prior written approval from the American Lung Association.

Equipment Repair & Service Contracts

No award shall be used for repair or service contract costs for institutional equipment.

Financial Report

At the conclusion of the award, the American Lung Association requires the completion of a financial disbursement report covering the entire award period and reflecting the award expenditures as originally approved. Any funds used for unauthorized expenditures or unexpended funds must be returned to the American Lung Association, with the disbursement report, within 60 days after the award has terminated. *The American Lung Association does not require a financial disbursement report to be completed at the end of each year of support.*

Human Subjects and Stem Cells

It is recommended that applicants submit projects to the appropriate human subjects Institutional Review Board at the time of application or before.

All research conducted on human subjects and/or human stem cells must comply with the provisions of the United States Department of Health and Human Services 45 C.F.R. pt. 46 to the same extent as each would were the research funded by the National Institutes of Health. Assurance of the Institution Review Board (IRB) approval and/or exemption and approved patient consent forms must be provided to the American Lung Association prior to the start of an award; otherwise the award may be administratively withdrawn.

If the proposed research project involves human subjects, the population sampled shall be inclusive of the general population, of relevance to the scientific question posed, without restriction in regard to gender, race, age, and socioeconomic status. Proposals that intentionally restrict the population sampled must include a compelling scientific rationale for such design.

Legal Liability

Neither the American Lung Association nor the Alpha-1 Foundation will assume any responsibility for and the grantee institution will indemnify and hold the American Lung Association and the Alpha-1 Foundation harmless from any lawsuit, claim, judgment, damages, awards, or malpractice arising from research or investigations related to an award as a condition of accepting this award.

Other Funding/Overlap

No other American Lung Association award may be held concurrently with the Alpha-1 Research Grant. An investigator who has previously received an American Lung Association Biomedical, Clinical, Social-Behavioral, Dalsemer Research Grant is not eligible for additional Research Grant support.

Awardees can hold active career development grants (such as K awards) but they may not hold an award of an established investigator or large grant (e.g., R01, VA Merit Review Award) at any time during their American Lung Association award.

American Lung Association funds shall not be used to duplicate any work supported by other funding agencies. ***It is the responsibility of the applicant/awardee to notify the American Lung Association of any potential budgetary or scientific overlap.*** This includes the receipt of a new award during the period of the Lung Association award. An assessment of the degree of scientific overlap is made on an individual basis. In cases of significant scientific overlap the awardee will have the option to choose between the American Lung Association award and that of the other organization.

Overhead/Indirect Costs

Overhead or indirect costs are not permitted.

Patent Policy

Inventions and discoveries from research performed during the term of this award will be subject to the current American Lung Association and Alpha-1 Foundation patent policy, as well as, to the patent policies of the institution where the work is performed.

Project Support Expenditures

No award shall be used for the purchase of furniture, computers, the construction or renovation of facilities, payment of honoraria, membership dues or tuition, purchase of textbooks or periodicals or payment for secretarial support.

Publications

All publications and/or presentations at scientific conferences and meetings based on research conducted from this award must acknowledge “the support of the American Lung Association and the Alpha-1 Foundation”. Reprints of abstracts, manuscripts, or other articles that reflect research conducted under this award must be submitted to the American Lung Association at research@lung.org.

Renewals and Progress Reports

Grants are subjected to annual review and may be granted for two years. The second year of support is based on demonstrating satisfactory progress, as well as, the availability of funding from the American Lung Association, and the Alpha-1 Foundation. Awardees are required to complete a Renewal Application for each year the award is subject to renewal.

Periodic progress reports may be requested and must be completed to assist the American Lung Association in shaping future policies with respect to its award program.

Tobacco Funded Research and Other Conflicts of Interest

Neither the American Lung Association nor the Alpha-1 Foundation will provide research or other funding to investigators who have received direct funding or funding from agencies of the tobacco industry. American Lung Association and Alpha-1 Foundation awardees must comply with the provisions of the United States Department of Health and Human Services regulations on financial conflicts of interest 42 C.F.R. pt. 50, subpt. F to the same extent as each would were the research funded by the National Institutes of Health.

American Lung Association Patents and Intellectual Property

- a. All inventions or intellectual property made with support in whole or in part by research or training grants or awards from the American Lung Association and/or the Alpha-1 Foundation must be reported at the earliest practical time to the Research Division. The grantee institution or individual awardee agrees to notify the American Lung Association immediately of the decision to apply for patents or other legal protection for intellectual property, and to consider seriously and in good faith any comments or objections the American Lung Association and/or the Alpha-1 Foundation may have concerning such applications. The Association and the Foundation agree to keep all information confidential and to not release any information relating to such

inventions, intellectual property or applications. All patenting expenses shall be borne by the grantee institution or individual awardee.

- b. Title to any invention or intellectual property shall reside in the grantee institution to the extent that such title is claimed by the institution under its patent policy or procedure and paragraphs c-h shall apply. If a grantee institution has no established patent policy or procedure for administering inventions or intellectual property, or if the institutional patent policy or procedure does not claim rights for the institution or individual inventor, then the American Lung Association and the Foundation shall have the right to determine the disposition of invention or intellectual property rights and paragraphs c-f shall not apply.
- c. Distribution of income derived from an invention or intellectual property which might include equity disposition shall be according to the policies of the grantee institution, although the American Lung Association and the Alpha-1 Foundation would expect to participate in income derived from the invention or intellectual property to the extent and at a rate of remuneration determined by mutual agreement between the grantee institution-the American Lung Association and the Alpha-1 Foundation no later than six months after first receipt of income. Such agreement shall be guided by the principle that the Association and Foundation's proportion of sharing in the income shall be reasonably related to the Association's and Foundation's proportion of support for the invention or intellectual property. As between the Association and the Foundation, all amounts shall be split between them 50/50.
- d. If any invention or intellectual property is made with the joint support of the American Lung Association and other organizations, it is expected that income distribution shall be in accordance with the provisions of the policy. Should an exception be taken to this provision, the grantee institution, the American Lung Association, and other sponsoring agencies will confer to reach a mutually satisfactory disposition of invention or intellectual property rights.
- e. No patent, patent application or other type of protection shall be abandoned without first notifying the Research Division. At such time, the grantee institution and individual awardee shall give the American Lung Association and the Alpha-1 Foundation, the opportunity to take title to the invention or other intellectual property.
- f. The grantee institution shall agree that when it licenses any invention or intellectual property it will obligate the licensee as follows: The licensee agrees to exert its best efforts to commercialize or cause to be commercialized the invention or intellectual property as rapidly as practical, consistent with sound and reasonable business practices and judgment. In the event that the licensee has failed to commercialize the invention or intellectual property within the number of years determined to be reasonable for the invention or intellectual property, the grantee institution upon conferring with the Association and the Foundation shall have the right to convert an exclusive license to a non-exclusive license or to terminate a non-exclusive license. If the licensee or grantee institution has an ongoing and active research, development, manufacturing, marketing or licensing program as appropriately directed toward the production and sale of the invention or intellectual property, the same would be deemed to be sufficient evidence that the licensee or grantee institution has commercialized the invention or intellectual property. Continued failure to commercialize as reasonably determined by the Association and the Foundation shall allow the Association and the Foundation, if they so elect, to assume ownership of the applicable invention or intellectual property.
- g. The American Lung Association and the Alpha-1 Foundation reserve the right to public acknowledgement for inventions or intellectual property resulting from support by the Association and/or the Foundation, as applicable; however, neither the American Lung Association name and logo-, nor the Foundation's name or logo may be used in association with an invention or intellectual property without prior approval of the Association or Foundation as applicable.
- h. The American Lung Association and the Alpha-1 Foundation may have use of inventions or intellectual properties without payment of royalties or fees, but solely for use within the Association and Foundation's charitable mission or for intramural purposes and not for any of its grantee institutions or individual awardees.

Alpha-1 Research Grant (A1) Application Guide

The American Lung Associations used the e-grantmaking website, proposalCENTRAL, to process all awards and grants applications. Please access this website at: <https://proposalcentral.altum.com>

For questions about the electronic application process, e-mail: pcsupport@altum.com

PROPOSAL SECTIONS

Title Page

To initialize your application, enter a title for your project. If you are resubmitting a proposal previously reviewed, but not funded, by the American Lung Association, select the appropriate application from the list of prior submissions. An applicant who is unsuccessful in a competition may resubmit the same or similar application up to two times.

Applicants are also asked to provide the first year monetary amount requested. Refer to the individual Program Descriptions for award allocation amounts. The project start and end dates are automatically entered for you as we do not allow flexible start dates. The American Lung Association award period is July 1, 2017 to June 30, 2018.

Once complete, press the red 'SAVE' button and watch the gray Proposal Navigation box on the left portion of your screen become activated. Click 'NEXT' or a section name to move to another section.

Download Templates & Instructions

All downloadable files are located on this page and consist of instruction files and required templates for your application submission. Click the 'DOWNLOAD' link for each file, and 'SAVE' to your computer. Go to the "Research Plan and other Supporting Documents" menu option in the gray navigation menu to upload your completed template files.

Enable Other Users to Access this Proposal

This section allows you to give other users access to your grant application. When you give a person access to your grant application, you can give them one of three levels of permissions: View (cannot change any details), Edit (can view and change information in the grant application, but cannot Submit or view the Access Permission page), or Administrator (can view, edit and submit the application, as well as give access rights to others).

Applicant Contact Information

The person who creates the application is the default Applicant. Contact information from this person's Professional Profile, including primary institution affiliation, is automatically loaded to this section of the application. As all American Lung Association correspondence occurs with the individual Applicant, please provide the correct contact information for the applicant. The Sponsored Research Program Office is **NOT** acceptable.

To change the Applicant and the institution affiliation, choose from the list of available names and institutions. For privacy reasons, the list contains only the following: the name and institution of the person who created the application and the names of individuals who included you in the Access Permissions section of their Professional Profile (such as administrators at the institution). If, after changing the Applicant you need to update the contact information that appears below it, you can click 'EDIT PROFESSIONAL PROFILE' to go directly to your Professional Profile. You can exit this screen and select the 'PROFESSIONAL PROFILE' tab from the proposalCENTRAL management window and changes will be automatically uploaded to the Applicant screen. Contact information and institution affiliation from the selected Applicant's Professional Profile is preloaded to the Applicant's contact information section below.

Complete all the required fields that are marked with a red asterisk. If the required fields are incomplete or incorrect, changes must be made in the Applicant's Professional Profile. You can go directly to the selected Applicant's Professional Profile by clicking the button 'EDIT PROFILE.' Alternatively, you may exit the Applicant's section and use the Professional Profile tab in your proposalCENTRAL management window which is usually located in a different proposalCENTRAL browser window than the application. **The percent of Applicant's total effort currently devoted to each of the listed activities must be indicated before going on to the next section.**

Institution and Contacts

The institution of the Applicant will be as selected as the default Institution and will have primary contractual responsibility for the grant if awarded. Institution information is pre-loaded to this section of the application. **NOTE: If the required fields marked by a red asterisk are incomplete or incorrect, changes must be made in the Institution Profile.** To change the Institution choose from the list of institutions and press the button 'CHANGE INSTITUTION'. Initially, the list contains only the following: the current institution, the institutions that you listed in your Professional Profile, and any other institutions that include your UserID in their Access list. Use the 'SEARCH' option to search the other institution profiles available in proposalCENTRAL. Results of the Search will be added to the list of institutions. To change the Institution choose from the new list of institutions and press the button 'Change Institution'. If, after changing the Institution you need to update the contact information that appears below it, contact the Grants and Contracts office of your institution to update the Institution Profile or call Customer Service at proposalCENTRAL at 1-800-875-2562 for assistance. Next, choose the appropriate institutional officials for the particular grant program; (*) indicates a required contact. There are two ways to enter contact information for the requested contact - you can select from the list of Institutional Officials from the Institution Profile of the Institution selected at the top of this page OR enter an email for the appropriate contact and complete and save the form. When you have selected the appropriate institution officials, click the red 'ADD' button. The contact information is loaded into your proposal and the contact will be shown in the table below. Be advised that the contact form may be pre-filled with some information if the email you entered is already associated with a proposalCENTRAL user.

Key Personnel

The applicant is responsible for listing all personnel who will have a significant role with the research project (i.e., will have impact on project content, data collection, data interpretation). **Mentors must be listed as Key Personnel. DO NOT** list the applicant in this section.

Steps for the Applicant to Submit Key Personnel:

- Enter the email address of the key personnel in the text box provided and click 'ADD'.
- A window will open; enter the requested information. Complete all the required fields that are marked with a red asterisk. If the person is already registered in proposalCENTRAL, some information will be pre-loaded into the contact form.
- Click the red 'SAVE' button and 'CLOSE WINDOW'.

Note: All edits and deletions to key personnel must be done in the Key Personnel table. Changes will be for this proposal only. Permanent changes must be made in the person's Professional Profile.

Letters of Recommendation

All applicants must provide **3** letters of recommendation. **Duplicate letters from the same person are not accepted and may be grounds for withdrawal.**

One of the three letters must be written by the applicant's Mentor and labeled as such. The Mentor's letter must acknowledge the mentorship of the applicant along with an explanation of the plan for the applicant's professional growth. The letter should explain the supervised experiences that would be offered to the applicant, the systems by which progress would be monitored, and how the awardee's progress would be evaluated.

Letters of Recommendation are critically important and should address the candidate's competence and potential to develop into an independent investigator. **The recommendation letters should be from individuals**

not directly involved in the application, but who are familiar with the applicant's qualifications, training, and interests. Only individuals who can make the most meaningful comments about the candidate's professional training and qualifications for a research career should be used as referees.

Steps for the Applicant to Contact the Referee:

- Enter the email address of the referee in the text box provided and click 'ADD.'
- A small window will open; enter the Last Name and First Name of the referee. If the referee is already registered in proposalCENTRAL, the name will automatically display in the window.
- Click the red 'SEND EMAIL' button and 'CLOSE WINDOW.' An email will be sent to the referee from proposalCENTRAL requesting a Letter of Recommendation. The email will include instructions and a link for the referee to upload the completed Letter of Recommendation, directly to your grant application.

You will see that once the email has been sent, referee information will be displayed in the accompanying table. You can refer to this table to check on the status of the letters that have been uploaded to your application. When each of the letters is uploaded, the status will display as 'SUBMITTED.' You may want to check periodically on the status of the referee letters. *Letters of Recommendation are to be completed and signed on institutional letterhead and 'UPLOADED' to the applicant's application in proposalCENTRAL by the Referee.* Electronic signature is permitted. After the applicant submits the application, letters of recommendation cannot be changed. The referee will not have access to any portion of your grant application in the upload process.

Please note: Recommendation letters are separate from the Department Head Statement required as part of the Research Plan. An application must have a total of 4 letters (3 recommendations and 1 Department head statement).

Project Summaries

General Audience Summary

Provide a succinct and accurate description of the research project in non-scientific terms that could be clearly understood by a general audience. Do not include any proprietary or confidential information.

Please observe the following limitations for the general audience summary:

- Limit the summary to 1,000 characters or less.
- Information entered in this field must be text only: scientific notations, special characters, special fonts, and other rich-text formatting (e.g., bold, italics, underline) cannot be saved or displayed.
- Please type continuously - do NOT click 'ENTER' at the end of each line. After cut and paste, check the text to make sure the lines are continuous. Click 'ENTER' to begin a new paragraph(s).

Technical Audience Summary

Provide an abstract of the research project in technical terms that would be appropriate for experts in the field. Do not include any proprietary or confidential information.

Please observe the following limitations for the technical abstract:

- Limit the abstract to 3,000 characters or less.
- Information entered in this field must be text only: scientific notations, special characters, special fonts, and other rich-text formatting (e.g., bold, italics, underline) cannot be saved or displayed.
- Please type continuously - do NOT click 'ENTER' at the end of each line. After cut and paste, check the text to make sure the lines are continuous. Click 'ENTER' to begin a new paragraph(s).

Scientific Categories

Select the most appropriate category(s) for your proposed project in order of relevance. Select choices carefully as they will partially be used to facilitate selection of scientific peer reviewers.

Assurances

All research funded by the American Lung Association must comply with federal requirements regarding the use of human subjects, animals or biohazards in research. *It is recommended that applicants submit projects to the appropriate Review Board at the time of application or before.*

Human Subjects and Stem Cells

Applicants/ awardees conducting research on human subjects and/or human stem cells must comply with the provisions of the United States Department of Health and Human Services 45 C.F.R. pt. 46 to the same extent as each would were the research funded by the National Institutes of Health.

Indicate whether the proposed project involves Human Subjects. If so, add the institutional OHRP Assurance Number as well as the individual proposal IRB status – “approved”, “exempt” or “pending”. If approved or exempt, please provide the corresponding date of approval or exemption.

Animal Use

The American Lung Association allows animal use in biomedical research only when no other means of obtaining scientifically sound, valid and useful results are available. Applicants/ awardees must comply with the Public Health Service Policy on *Human Care and Use of Laboratory Animals* and the National Research Council *Guide for the Care and Use of Laboratory Animals* to the same extent as each would were the research funded by the National Institutes of Health.

Indicate whether the proposed project involves vertebrate animals. If so, add the institutional Animal Welfare Assurance Number as well as the Institutional Animal Care and Use of Committee (IACUC) status – “approved”, “exempt” or “pending”. If approved or exempt, please provide the corresponding date of approval or exemption. Also, indicate whether or not the institution has been accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC). Applicants from institutions that do not have an IACUC or accreditation from the AAALAC are not eligible to apply.

Biohazards

Biohazards are broadly defined to be recombinant and/or infectious and tumor materials that may be deleterious to normal organisms upon controlled exposure.

Indicate on the electronic application the Institutional Biosafety Committee (IBC) status. If approved, please provide the corresponding date of approval on the electronic application. If “exempt” from IBC approval within your institution, place “exempt” and the date the exemption was approved.”

Research Plan and Other Supporting Documents

Part I. Templates and Uploaded Files (attachments):

Click the ‘DOWNLOAD’ link for each template file, and ‘SAVE’ to your local workstation to complete.

Using the Provided Templates

Before submitting an application, the following components must be uploaded to proposalCENTRAL. All components of the application require the use of provided templates also available on this page. All the required attachments are listed in the section directly above the templates section. This display is merely a tool to help you keep track of your completed *required* files. Once you upload a completed “required” template, the template name will display in the “Current List of Uploaded Attachments.”

The ‘VALIDATE’ link in the Navigation Menu of the online application serves as a tool to check that all *required* attachment files are included in your application. *The Validate link will also check for any missing required online entries.*

Language and Format Requirements

All applications must adhere to the following language and format requirements. *Not adhering to these requirements may result in an application being administratively withdrawn.*

- ✓ The applicant’s name should always be in the top ‘HEADER’ portion. The header information should carry forward to subsequent pages in the template.
- ✓ Use English only and avoid jargon and any unusual abbreviations. Your application should read like a Scientific American journal article.
- ✓ Use Arial 11 point font size, the NIH-suggested font, unless otherwise specified in the instructions for a specific template.

- ✓ Be consistent with the use of font styles and indentation.
- ✓ Type density, including characters and spaces, must be no more than 15 characters per inch (cpi). For proportional spacing, the average for any representative section of text must not exceed 15 cpi.
- ✓ No more than 6 lines of type within a vertical inch.
- ✓ Margins, in all directions, must be at least ½ inch.
- ✓ Figures, charts, tables, figure legends, and footnotes may be smaller in size but they must be clear and legible.
- ✓ Applicants are responsible for correcting any changes to templates resulting from input of data. Data should be completed in the space provided. Each template page must respect the original margins on all sides.
- ✓ Attached files should be no larger than 3-5 MB to facilitate review of the application. Very large files can make a full and comprehensive review of the application difficult. The objective is to find a balance between the content of your application and file size.

Uploading to Online Application

Attachment files must be submitted and uploaded to electronic application as PDF files. Once attachments are uploaded, you will get a confirmation message and see that your file is now listed in the “Uploaded Attachment” section of the screen. Two links are available in each row of an uploaded attachment: **DEL** and **SHOW**. “Del” allows you to delete the file, if necessary, and “Show” opens the uploaded file. It is strongly recommended that you **open and review** your uploaded file. If, for any reason, you wish to modify the file, make the revisions in the **original** document (offline), **convert** the file to PDF and once again, **attach** the newly revised file. **Remember to delete any previously submitted versions of the file.**

Part II. Biographical Sketch

Using the template provided, submit biographical sketches for the applicant and all key personnel listed in Section 6, including the applicant’s mentor. **Biographical Sketches must not exceed four (4) pages for each person and should provide the following information about each key person, starting with the applicant:**

Personal Statement: Briefly describe why your experience and qualifications make you particularly well-suited for your role in the project that is the subject of the application. Also, briefly describe any changes in primary field of interest and/or career gaps due to personal or professional circumstances that may have affected your scientific advancement or productivity.

Positions and Honors: List in chronological order previous positions, concluding with your present position. List any honors.

Selected peer-reviewed publications (in chronological order and no more than 15): Do not include manuscripts submitted or in preparation; abstracts or posters. Please choose selected publications based on most recent, importance to the field, and/or relevance to the proposed research.

Research Support: List selected ongoing or completed (during the last three years) research projects (federal and non-federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.

Part III. Budget and Justification

Using the template provided, submit a budget and justification for your research project. Awards are only given in one year increments but all awardees will be given the opportunity to renew their project for a second year of funding. *Funding is contingent on individual progress during the award year and the availability of funds.* Applicants must to request an amount appropriate for the specific award.

Budget Spreadsheet

The first page asks the applicant to estimate direct costs for the first year of the proposal only. The second page asks the applicant to estimate direct costs for the entire period of the award. Indirect costs are **not** allowed for any American Lung Association award. Where applicable, only indicate dollars (**no cents**).

Personnel: For junior-level Investigator Awards there is an institutional base salary limitation of \$199,000. Fringe benefits may be requested provided such are treated consistently by the applicant's organization as a direct cost. No more than 75% of funds may be used for an awardee's salary and/or fringe benefits. There are no salary caps for other personnel.

Equipment: Itemize equipment with costs. Equipment is defined as an item that costs \$500 or more, has a primary function related to the research project, and ordinarily has a usable life expectancy of one year or greater. No more than 30% of the total award budget may go to fund the purchase of permanent equipment.

Supplies: Itemize supplies with costs. For example, indicate the number of experimental animals to be used, unit cost per animal, and cost for daily use.

Discretionary Funds: No more than \$2,500 per annum may be used for travel; publications; supplies or other expenses directly related to the American Lung Association- funded project and within the award terms and conditions.

Other Project Support Expenses: No award shall be used for the purchase of furniture, computers, the construction or renovation of facilities, payment of honoraria, membership dues or tuition, purchase of textbooks or periodicals or payment for secretarial support.

Total Costs may not exceed allowable award amounts. Correct arithmetic is the applicant's responsibility.

Budget Justification: Please provide a justification for the proposed budget for the **first year** only. **The budget justification must not exceed three (3) pages.**

Part IV. Resources

Using the template provided, describe the institutional resources available for the project. **The resource section must not exceed two (2) pages.**

Facilities: Specify the facilities to be used for the conduct of the proposed research. Indicate the performance sites and describe capacities, pertinent capabilities, relative proximity, and extent of availability to the project. Under "Other," identify support services such as machine shop, electronics shop, and specify the extent to which they will be available to the project. Use continuation pages if necessary.

Equipment: List the most important equipment items already available for this project, noting the location and pertinent capabilities of each.

Part V. Other Support

Using the template provided, list any and all active and pending support for each key personnel. **No page limit applies to the Other Support information.**

Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. **Please specify who the Primary Investigator is for all other support listed.** Prizes or gifts do not need to be included. Providing a list of current or pending training awards is only necessary for Research Training Fellowship applications.

The American Lung Association will not award funds to duplicate any work that is being supported by other funding agencies. Budgetary overlap is **not** permitted; however, scientific overlap will be evaluated on an individual basis. In cases of significant scientific overlap a successful applicant will have the option to choose between the American Lung Association award and that of the other organization.

Part VI. Resubmission Statement

Resubmissions are applications previously reviewed that were not selected for funding in a prior application cycle. An applicant who is unsuccessful in a competition may resubmit the same or similar application up to two times. **If major changes are made to the application or if this is an entirely different/new project, it should not be checked as a resubmission.**

Using the template provided, explain how the application has been strengthened or modified from the original. This statement must also include responses to criticisms and issues raised in the review critiques for the previous application. When an application is checked as a resubmission, it will be assigned to at least one of the previously assigned peer reviewers, whenever possible. Include sufficient information to permit an effective review without reviewers having to refer to previous versions of your application. **The Resubmission Statement must not exceed two (2) pages.**

Part VII. Research Plan

Please note: Page limits, language and format requirements listed in the Language and Format Requirements must be adhered to in preparing your research plan. Not adhering to format and page limitations may result in an application being administratively withdrawn.

Specific Aims: 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. **The Specific Aims section must not exceed one (1) page.**

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.

Aims must not be too general, such as “*To define the determinants of maximal expiratory flow,*” but rather “*To study the influence of static lung recoil on maximal flows.*” Your statement should be limited to what can be accomplished during the award period.

Research Strategy: Organize the Research Strategy in the specified order using the instructions provided below. Start each section with the appropriate section heading — Significance, Innovation and Approach. Cite published experimental details in the Research Strategy and provide the full reference in the References section. **Applicants are limited to 6 pages.**

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.
- Explain how this research will impact your future goals or directions, as long as a clear distinction is made between your immediate and long-range plans.

Innovation

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms. This provides an opportunity to demonstrate your knowledge and ability in this area, and to synthesize large volumes of information into a succinct and cohesive statement.
- 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. Clearly synthesize your own contributions to the field, and demonstrate your relative stature in the area.
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

Approach

- Explain why you have chosen to address a particular portion of the overall problem and why you have chosen a particular approach. Discuss your preliminary studies, data and/or experience pertinent to this application and specify all novel data.
- Describe the overall strategy, methodology, and analyses to be used to accomplish each of the specific aims of the project. For each aim, include how the data will be collected, analyzed, and interpreted (e.g., number of experiments, types of measurements to be made).
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. This should include discussion of what you will do if conflicting and contradictory data are obtained.
- 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.

Assurances: State concisely how assurances will be met within the confines of the proposed research project. Assurances must not exceed two (2) pages.

Human Subjects: When human subjects or material obtained from such subjects are used in the proposed project, the application must state how the rights and welfare of the individual subjects are protected and assured. Include consent forms and questionnaires in appendix, if applicable. If the proposed research project involves human subjects, the population sampled shall be inclusive of the general population, of relevance to the scientific question posed, without restriction in regard to gender, race, age, and socioeconomic status. Proposals that intentionally restrict the population sampled must include a compelling scientific rationale for such design.

Animal Use and Justification When animals are used in the project, the application must include a succinct and complete description of the following five points:

- Provide a detailed description of the proposed use of the animals in the work outlined in the Research Strategy section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
- Justify the use of animals, choice of species and numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
- Provide information on the veterinary care of the animals involved.
- Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.
- Describe method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations.

Biohazard Materials

When biohazard materials, defined as recombinant, infectious and tumor selected agents (i.e. radioisotopes) that may be detrimental to normal organisms upon controlled exposure are used:

- Describe procedures that will be used to monitor possession, use and transfer of the Select Agent(s).
- Describe plans for appropriate biosafety, bio-containment and security of the Select Agent(s).
- Describe the bio-containment resources available at all performance sites.

References: **References must not exceed five (5) pages.**

Appendix: May contain additional and relevant material such as letters of support, questionnaires and/or consent forms. No other material such as preliminary data, photographs/images or publications, is allowed in the appendix. **The appendix is limited to 5 pages.**

Part VIII. Department Head Statement Letter

Please note: The Sponsor and/or Department Head Statements are separate from the 3 Letters of Recommendations required. **A Department Head Letter is required on Institutional Letterhead**

Content of Department Head Statement:

1. State the applicant's current and projected status during the initial term of the award.
2. State the applicant's faculty title and from what academic institution does the applicant currently hold his/her faculty appointment. **The Department Head Statement must be explicit as to whether or not the applicant currently holds a faculty appointment, and/or if the applicant will be promoted to faculty between the time of application and award commencement. Without the confirmation of faculty status, the applicant will be disqualified.**
3. State the applicant's future path at your institution and plan for academic development.
4. State your department's financial and space commitment to the applicant's career, and to the American Lung Association's project being submitted.
5. Describe the intellectual environment and your involvement in the applicant's award.
6. Guarantee that the budget does **not** overlap with any existing or pending support of the application's collaborations (including NIH-type other support information, from all collaborating scientists).
7. State minimum percent of overall effort and guaranteed time to be protected for research.
8. State whether you also function as the applicant's mentor.

Part IX. Significance to the American Lung Association Mission

Using the template provided, produce a one page narrative as to how your proposed research project will help support the American Lung Association's mission "To Save Lives by Improving Lung Health and Preventing Lung Disease" and our mission-related Strategic Planning Goals of:

- Eliminating tobacco use and tobacco-related lung diseases
- Improving the air we breathe so it will not cause or worsen lung disease
- Reducing the burden lung disease on patients and their families
- Defeat lung cancer

Part X. Certification Form

Prior to submitting an application, an applicant must obtain signatures (electronic signature is allowed) from key officials certifying compliance with American Lung Association policies and requirements, including the following Conflict of Interest Clauses:

Tobacco Use: The American Lung Association will not provide research or other funding to investigators who have received direct funding or funding from agencies of the tobacco industry.

Financial Disclosure: American Lung Association applicants/awardees must comply with the provisions of the United States Department of Health and Human Services regulations on financial conflicts of interest 42 C.F.R. pt. 50, Subpt. F to the same extent as each would were the research funded by the National Institutes of Health. In general, the purpose of the Conflict of Interest policy is to ensure that there is no possibility that an applicant or their family will receive financial gain as a result of American Lung Association supported research.

Part XI. Required Citizenship and Optional Demographics

At the time of application, candidates must be United States citizens or foreign nationals holding one of the following visa immigration statuses: permanent resident (**Green Card**), exchange visitor (**J-1**), temporary worker in a specialty occupation (**H-1B**), Canadian or Mexican citizen engaging in professional activities (**TN**), Australians in Specialty Occupation (**E-3**) or temporary worker with extraordinary abilities in the sciences (**O-1**). At the time of application and throughout the award, an applicant must be employed by a U.S. institution.

Please note that the information under Optional Demographic Information will be used only for statistical purposes and will not be provided to the reviewers.

Part XII. Validate

Click the 'VALIDATE' link (from any page of the online application). Validate checks for missing **required** information or files. Any missing required information will be listed on the screen. All required information must be supplied before you can **Submit** an application.

Part XIII. Submit (Last Step)

The American Lung Association **requires** all applications to be submitted electronically through proposalCENTRAL. Once you have completed and validated your application, you can then 'SUBMIT' electronically to proposalCENTRAL. **The deadline for submission is: December 15, 2016.**