Guidelines for 2015 Research Grant Applications

RESEARCH GRANT

| DESCRIPTION                                                                 | The objective of this grant is to provide funds to encourage the development of new information that contributes to the understanding of alopecia areata. Consideration will be given to those projects that provide insight into new therapies. All proposals must be hypothesis generating or hypothesis testing and provide sufficient preliminary data to justify the National Alopecia Areata Foundation’s support. |
| INSTITUTIONAL ELIGIBILITY                                                  | Public or private institutions throughout the world such as universities, colleges, hospitals and laboratories; and for-profit and non-profit corporations |
| APPLICANT ELIGIBILITY                                                      | Required: MD, DO, PhD or equivalent and faculty position or equivalent |
| TERMS                                                                      | $100,000 maximum/year for up to two years |
| DEADLINE                                                                  | August 1, 2015 at 5:00 pm ET |

HOW TO APPLY


Optional Letters of Inquiry (LOIs): The deadline to submit an optional Letter of Inquiry (LOI) is June 1, 2015. Submitting an LOI is optional and not required prior to submission of a full application.

1. Applicants may choose to first submit a brief Letter of Inquiry (LOI) summarizing the aims and relevance of the proposed research and the qualifications and resources of the applicant(s) in sufficient detail for evaluation.
2. The LOI will be reviewed and the applicant will be notified within four weeks if a full application is warranted.
3. Upon request for a full application, applicants should follow these Guidelines to complete and submit a full Investigator-Initiated Grant Application.
4. Optional LOIs and/or Investigator-Initiated Grant Applications should be submitted by email to: abby@naaf.org.

For additional information concerning our current funding opportunities, please visit <insert link to Apply for a Research Grant>, or contact the NAAF research coordinator by email at abby@naaf.org or phone at 415-472-3780.
## RESEARCH FUNDING PRIORITIES

NAAF’s Research Funding Priorities are based on targeted research aims set forth at the 2014 Alopecia Areata Research Summit, *From Targets to Treatments: Bridging Autoimmune Research to Advance Understanding of Alopecia Areata*, held December 4-5, 2014 in Bethesda, Maryland. This meeting brought together leading experts with new investigative partners to discuss recent discoveries and to identify opportunities to advance alopecia areata research, and yielded the following Research Funding Priorities:

### Immunology & Autoimmunity
- Continue research to advance understanding of mechanisms of disease, including roles of dendritic cells, antigen-presenting cells, macrophages and early innate immune response, which could lead to discoveries for early intervention and prevention.
- Identify T-cell receptors and the antigens/epitopes they recognize that are driving the disease. These could be used as predictive markers or as targets for antigen specific therapeutics.
- Begin collecting samples (white blood cells, peripheral blood mononuclear cells and swabs) useful for functional and genetic assays for the Alopecia Areata Registry, Biobank and Clinical Trials Network (the Registry). Work with the Immune Tolerance Network to develop standardized protocols for freezing and banking samples.
- Investigate the potential use of antibodies, cytokines, or other molecules to serve as predictive biomarkers for alopecia areata and correlate T-cell responses with therapeutic responses.
- Study regulatory T cells for potential use as predictors of hair regrowth or response to therapy.
- Investigate the role of chemokines regulating autoreactive homing in alopecia areata.
- Further study the relationship between other autoimmune diseases and alopecia areata.
- Further study the mechanistic relationship between thyroid dysfunction and thyroiditis and alopecia areata.
- Investigate the role of inflammasomes in alopecia areata.

### Genetic Developments and Therapeutic Targets
- Focus on expanding the Registry to 10,000+ DNA samples for deep sequence analysis to identify new candidate genes and variants and determine the downstream impact.
- Study the epigenetics of alopecia areata and investigate the role of race and ethnicity.
- Undertake additional biomarker studies and determine a genotype risk score.
- Study gene expression of patchy alopecia areata and investigate parallels between regional beta cell destruction in Type 1 diabetes.
- Investigate the role of epigenetics, environment, and triggers in discordant twins.
- Study the role of CD4 T cells in alopecia areata.
- Collaborate with international databases/repositories for the use of samples from diverse populations.
- Apply to NIH for funding of large-scale genome sequencing studies.

### Animal Models
- Expand research to identify better humanized animal models to minimize graft-vs-host disease (GVHD) as current models are often difficult to reproduce.
- Develop models that use induced pluripotent stem (IPS) cells from patients to perform drug screening.
- Facilitate contracts between academics and industry and the coordination of resources.
- Develop standardized protocols for more reproducibility and begin pilot studies in basic and preclinical trials.
New Technologies and Directions
- Perform a literature review and industry scan to identify the status of epitope and microbiome research in alopecia areata and related diseases.
- Create a Microbiome of the scalp of control and alopecia areata patients’ database using Next Generation Sequencing of 16s RNA.
- Analyze the regional and geographical pattern of alopecia areata to study the epidemiological, ecological, and environmental factors related to microbiome diversity.
- Investigate differentially expressed proteins in hair follicles and nerves using proteomic approaches.
- Utilize the Immune Epitope Database (IEDB) analysis resource to generate predicted epitopes and sets of specific predicted epitopes from proteins identified in the above action item for testing in alopecia areata.
- Leverage available technology in infectious diseases and allergies to generate targeted experimental data using alopecia areata blood samples to screen the epitope sets described in the above action item.

Clinical Aspects, Epidemiology and Tools
- Modify the Core Uniform Protocol to expand age ranges and duration of hair loss criteria for inclusion.
- Collaborate with pharmaceutical companies, both large and small, to supply drugs to be tested and facilitate larger trials with more patients.
- Estimate burden of disease and annual cost to payers to entice insurance companies for coverage as well as pharmaceutical interest.
- Publicize information about disease burden and collaborate with the American Association of Dermatologists to disseminate data quickly.
- Advocate for insurance coverage of systemic or topical JAK inhibitors and partner with PCORI for comparative effectiveness research.
- Survey patients and medical professionals to capture clinical data about off-label use of JAK inhibitors and other potential therapies.
- Encourage and support medical professionals in obtaining Institutional Review Board approval to prospectively capture efficacy and safety data for alopecia areata patients treated off label with JAK inhibitors and other potential therapies.
- Study connections between alopecia areata and other systemic autoimmune diseases such as hypothyroidism.
- Investigate response to therapy among different ethnic groups.
- Collaborate with investigators performing clinical studies and develop a unified database to capture information.
- Improve communication between patients and caregivers, including sensitivity training about emotional impacts to facilitate information sharing.
- Improve privacy and emotional sensitivities of survey tools to validate potentially underestimated prevalence and incidence statistics.

GRANT REVIEW PROCESS

Once submitted, a grant application undergoes a two-step, single-blind review process to determine its eligibility for funding. NAAF reviewers adhere to conflict-of-interest and confidentiality requirements that are intended to promote an unbiased review process by minimizing even the appearance of a conflict of interest and by restricting the use of privileged application and review information.

Process Description

- A qualified scientific Chair is appointed to guide and facilitate the entire grant review process as a non-voting member.
- Initial review of an application is an evaluation of the proposal’s scientific and technical merit, and is conducted by an external Merit Review Committee comprised of experienced scientific reviewers (i.e., members of the extramural research community) and patient advocates (i.e., individuals with alopecia areata, caregivers and family members). Each application is reviewed by one patient and two scientists. The Chair assigns reviewers to each application based on relevant scientific expertise and/or applicable clinical or research experience. Reviewers address established criteria to independently critique and assign numerical scores based on merit.
- Applications and critiques are further discussed and re-scored at the Merit Review Committee meeting. Following the meeting, a summary statement report for each application is prepared that includes the reviewers’ written critiques, recommendations of the group and the average final score. The summary statement is sent to the Integration Panel for programmatic review, and to the applicant with decline/award notices.
- During the second level of review, conducted by the Integration Panel (IP), highly scored applications are assessed based on programmatic priorities and budget constraints. This panel is composed of key NAAF stakeholders, patients and scientists. The IP considers the initial Merit Review Committee’s conclusions and assesses the relevance to NAAF’s existing research portfolio and priorities in light of budget constraints. The final IP funding recommendation is presented to NAAF’s Board of Directors.

NOTIFICATION AND DISTRIBUTION OF AWARD FUNDS

Letters of Award or Decline will be sent via email in November 2015. The first Award Payment shall be made after NAAF receives the signed Award Agreement (provided with Letters of Award). Subsequent award payments shall be made in accordance with NAAF upon timely receipt of quarterly Progress Reports showing milestones met. Failure to achieve milestones or satisfactorily explain challenges may result in delay or withholding of payment.

INSTRUCTIONS FOR COMPLETING APPLICATIONS

1. Format Specifications for all application components:
   a. Type application in black ink using a standard, readable font such as Calibri, Arial, Helvetica, Palatino, Garamond or Times New Roman with a font size of 11 points or larger. Symbol fonts may be used to insert Greek letters or special characters. Smaller type is acceptable in figures, graphs, charts, tables, legends and footnotes, but these must be in black ink and readily legible.
   b. Use standard 8 ½ x 11 paper with at least half-inch margins on all sides, a single column format, single sided, single spaced with consecutively numbered pages.
   c. Limit the Research Plan section of the application, including literature cited, to ten (10 pages).

2. Face Page: The Face Page includes the main identifying information for the application including:
   a. Contact information for the Applicant and, if applicable, a primary Co-investigator.
   b. Project information including dates, proposed budget and amount requested in this grant application for the signing official for the institution should be the address to which the check should be sent.
The original completed Face Page with original signatures must be mailed to the National Alopecia Areata Foundation even if the application is submitted via email. Photocopies or stamped signatures will not be accepted. Scanned signatures will be accepted.

3. **Abstracts:** Please provide two abstracts describing the nature of this work and its importance to alopecia areata:
   a. One Lay Abstract to inform non-scientific members of the alopecia areata community and the lay public; and
   b. One Scientific Abstract to inform the scientific community.
   c. Limit each abstract to no more than 250 words.

4. **One Page Description:** In one page or less, describe the nature of this work and its importance to advancing understanding of and developing a treatment or cure for alopecia areata. Put this project in the context of what we know and what we need to know about alopecia areata and the autoimmune, skin and hair research landscape at this time.

5. **Research Plan:** This section should describe the Research Plan in sufficient detail to permit effective review for scientific merit, achievability, relevance, significance and breakthrough potential. Make every effort to be succinct while describing your project in sufficient detail to support evaluation. Do not submit a copy of an application prepared for another granting agency, copies of previous publications, or other supplemental documents. This section is limited to 10 pages, including literature cited.
   a. **Specific Aims and Hypotheses:** State concisely and realistically what the research described in this application is intended to accomplish during the period of the grant, including the hypotheses to be tested or the need(s) to be fulfilled. Not to exceed one page.
   b. **Background and Significance:** Why is the research important? Evaluate existing knowledge in the field and specifically identify the possible contributions that your investigation may make. Most importantly, how will your study help our understanding and lead to improved treatment of the patient with alopecia areata or a cure? State how scientific knowledge and clinical practice will be advanced if the aims of the research project are achieved.
   c. **Preliminary Results:** If applicable, explain any preliminary results found by you or others in this field that lead you to believe this project has merit.
   d. **Research Design and Methods:** Explain the methods by which you will accomplish the specific aims of the research project. Describe in detail the experimental design, the procedures to be used, and the manner in which the data will be collected, analyzed and interpreted. If new methods, techniques, or procedures are to be used, explain their potential advantages over existing methodologies. Discuss potential difficulties and/or limitations of proposed procedures and alternative approaches to achieve aims.
      i. Point out any procedures, situations or materials that may be hazardous to personnel or patients and the precautions to be exercised.
      ii. If clinical studies are involved: Provide details of the methods for patient selection and care; and, if hair re-growth is an efficacy measure, please reference and cite evaluation criteria in the NAAF Uniform Protocol, the “Alopecia areata investigational assessment guidelines” article from the 1999 JAAD, and the “Alopecia areata investigational assessment guidelines-Part II” from the 2004 JAAD in your application.
      iii. Include a timeline for the project.
   e. **Responsible Conduct of Research:** Applications must demonstrate sufficient training or include a plan for obtaining instructions in the responsible conduct of research, including the rationale, subject matter, appropriateness, format, frequency and duration of instruction.
   f. **Consultant or Collaboration Arrangements:** If the proposed project includes consultant arrangements and/or collaboration with other individuals outside the applicant’s group, describe the working relationships and support this description by letter(s) of intent or contract(s) signed.
by collaborating individuals. If clinical material required for this grant is to be furnished by other individuals, include a statement from these individuals agreeing to their participation and precautions taken to ensure anonymity of patients.

g. **Literature Cited:** List resources cited in this application in alphabetical order by first author in the following format: Author (Year). *Title of Article*, Title of Journal, Month/Issue: page(s).

6. **Proposed Progress Report Milestones:** Please propose at least two measurable milestones on which progress can be evaluated at 4 months, 8 months and 12 months. These milestones are not expected outcomes of the research, but actions that will have been completed and documented which demonstrate timely and effective progression of the research. Reporting on completion or satisfactory explanation of challenges in meeting these milestones is a condition of receiving ongoing payments.

7. **Detailed Budget:** Please complete a detailed budget for each year of support requested (maximum of two years). Please include the full cost of the proposed research project in the detailed budget even if you are only requesting partial funding from NAAF.
   a. Personnel – designate the percentage of the Applicant’s time that will be devoted to this project. If the salary is supplemented by other agencies, the percent of salary requested must be equal to or less than the percent of time allotted to this project. If support is requested for a co-investigator and/or technician, identify the amount of time these individuals will devote to the study.
   b. Supplies – Includes items such as glassware, chemicals, etc.
   c. Travel – Include purpose and cost of up to $750 in travel needed for the research.
   d. Animal Purchase and Care – State the number, unit purchase cost and unit care cost.
   e. Patient Care Costs – for human subject research, state the number of subjects and the estimated care cost per patient.
   f. Other Expenses – itemize other expenses by major categories, such as duplication, publication, computer, equipment maintenance, etc.

8. **Budget Justification:** Use this page to describe the nature of costs listed in the Detailed Budget under each major category and why they are needed. Also note how the money from this award will be used toward the total costs in each major category and how any additional money needed to complete the research will be obtained.

9. **Questionnaire:** Provide answers to these questions to help NAAF understand how this project fits with other work that has and will be done by the applicant and any history of previous research conducted with NAAF funding.

10. **Other Current and Pending Support:** Describe all funding that the Applicant and laboratory receive or expect to receive whether or not it is related to the research project proposed for this award. For each funding stream, identify the Source, amount, start and end dates and relationship to the research project proposed for this award. No page limit to this section.

11. **Previous Training and Experience and Future Plans:** Provide a brief summary of research and clinical fellowship training, clinical and research experience and future plans – including the reasons for entering fields related to alopecia areata research. Demonstrate interest and commitment to alopecia areata research and care, and to pursuing a career in academic medicine or research. Not to exceed 5 pages.

12. **Biographical Sketch:** Complete a Biographical Sketch for Applicant and any other key project personnel. Use the format provided by NAAF in the Application or use an NIH-style biosketch with references limited to those relevant to this project and identified as requested in the “Literature Cited” portion of the “Research Plan”. For the purposes of this application, NAAF defines key project personnel as anyone...
with an advanced degree who will play an instrumental role in the accomplishment or the project. Each complete Biographical Sketch should not exceed 3 pages.

13. Letters of Reference and Support: Please include up to three letters of reference or support that speak to the ability of Applicant and key personnel to conduct the proposed research. These letters should discuss scientific and clinical abilities, interests, and potential and attest to the academic qualifications, research experience, motivation and commitment to alopecia areata research.

14. Institutional Commitments and Requirements Letter: A signed letter from the appropriate sponsoring institution official must accompany this application to verify that research conducted in accordance with this award has met the institutional requirements for the following:
   a. An Institutional Review Board (IRB) has reviewed and approved the procedures for the use of human subjects, or human organs, tissues and body fluids, in the proposed research, in accordance with Department of Health and Human Services policies. Include the IRB number and a copy of the approved form with the letter, or indicate that the protocol is pending and will be approved before work is begun.
   b. A DATA SAFETY MONITORING PLAN (DSMP) for any proposed study that places human subjects at more than minimal risk.
   c. A plan to include, recruit and retain subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research.
   d. Research Involving Recombinant DNA meets the requirements contained in the document NIH Guidelines for Research Involving Recombinant DNA Molecules (revised April 2002).
   e. Research Involving Animals meets the guidelines of the National Institutes of Health, U.S. Public Health Service, which require that all proposed studies be reviewed and approved by an Institutional Animal Care and Use Committee (IACUC). If applicable, please provide the federally approved Animal Welfare Research Number, and the IACUC letter of approval, or indicate that the protocol is pending and will be approved before work is begun.
   f. A plan to assure adequate protection for any Biohazards involved in the research.

15. Additional Material: If you feel that they will be helpful to reviewers in assessing the worthiness and feasibility of the proposed research project, the items listed below may also be submitted with the application. Extensive appendix materials may not be reviewed. Please include only the most relevant documents from the following list:
   a. Letters of Collaboration (if applicable)
   b. For research involving human subjects, a copy of the IRB application and patient consent forms.
   c. Other materials pertinent to the grant proposal not already described.
COMPLETE APPLICATION CHECKLIST

☐ Face Page
☐ Lay and Scientific Abstracts (not to exceed 250 words each)
☐ One Page Description
☐ Research Plan (not to exceed 10 pages)
☐ Proposed Progress Report Milestones
☐ Detailed Budget
☐ Budget Justification
☐ Questionnaire
☐ Other Current and Pending Support
☐ Previous Training and Experience and Future Plans
☐ Biographical Sketch
☐ Letters of Recommendation
☐ Institutional Commitments and Requirements

The application and supporting materials must be submitted via email to Abby Ellison at abby@naaf.org.

National Alopecia Areata Foundation
65 Mitchell Boulevard, Suite 200-B
San Rafael, CA 94903 USA
415-472-3780
www.naaf.org