

New and Established Investigator Grant Application Instructions

**DEADLINE FOR SUBMISSION: September 15, 2025, 5:00 p.m. Eastern Time (U.S.)** 

Applications must be received at the National Scleroderma Foundation by September 15, 2025 (5 p.m. Eastern Time).

### APPLYING FOR THE NEW OR ESTABLISHED INVESTIGATOR GRANT

- Carefully and thoroughly review this entire document before completing and submitting your grant proposal.
- Grant applications that do not meet these quidelines or are incomplete will not be reviewed.
- Download the grant application from our website <a href="www.scleroderma.org/researchapply">www.scleroderma.org/researchapply</a>.
- Complete the application in its entirety and save to a PDF file as follows: LAST NAME, FIRST NAME\_EST (or NEW) APPLICATION
- The appendix should be saved as a separate PDF file as follows: LAST NAME, FIRST NAME\_APPENDIX

### SUBMITTING YOUR APPLICATION

Applications should be submitted by Upload to the secure Dropbox folder only accessible by the National Scleroderma Foundation Research Administrator. Upload should include only PDF files of Application and Appendix.

### CONFIRMING RECEIPT OF YOUR APPLICATION

Applicants should not consider their application received until they receive an email from the National Scleroderma Foundation confirming receipt. The Foundation will send confirmation emails to all applicants within 48 hours of receipt. If you do not receive an email confirmation, please email <a href="mailto:research@scleroderma.org">research@scleroderma.org</a>.

### **PEER REVIEW CRITERIA**

Applications will be reviewed and scored by the Foundation's Peer Review Committee. Reviewers will evaluate applications based on NIH guidelines for review that include evaluating strengths and weaknesses of the application. Innovation, Significance, Approach, Investigator(s), and Environment are considered.

### **FORMAT GUIDELINES**

Please submit application and appendix in PDF format. Appendices should not be used to subvert the page limitation on the grant. The height of the letters must be 11 point or larger. 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 six lines of type within a vertical inch. Margins may not be less than 0.5 inches.

### **DETAILS OF PROPOSAL**

Proposals should contain all ten (10) sections of the application. Please present them in the following order according to instructions:

## 1. Face Page (Page 1):

The face page is a separate page and must include the following:

- 1. Title of research grant application
- 2. Name, address, telephone number, fax number and email of Principal Investigator who will be responsible for the scientific conduct of the project (to be used for all future correspondence).
- 3. Grant type: New Investigator or Established. Is the proposal a re-submission? Check Yes or No

**Note**: No more than 1 resubmission incorporating critique comments and recommendations from prior submission will be accepted

- 4. Will human subjects be used in the proposed research? Check Yes or No. If YES, include a Human Subjects section with your application. The Human Subjects section is required and will not count towards the research plan page limit. Also attach copies of all research assurance approvals, consent forms, and statement of compliance with government requirements.
- 5. Will vertebrate animals be used in the proposed research? Check Yes or No. If YES, attach statements of compliance with American Veterinary Medicine Association and NIH guidelines, and complete Vertebrate animals section. ALL compliance approvals must be completed at time of grant award and submitted to the National Scleroderma Foundation, or the grant will not be funded.
- 6. Dates of proposed period of support. Grants are funded for April 1 through March 31 for each year of the award.
- 7. Funds requested for first year grant period: (Direct and Indirect Costs).
- 8. Funds requested for all years of support (Direct and Indirect Costs).
- 9. Name, address, and telephone number of the applicant organization and/or Performance Site(s) where the research will be conducted.
- 10. Type of organization (Check appropriate boxes).
- 11. Name, title, address, telephone number, and email of institution's Financial Officer, who will be responsible for the proposed grant funds, and required reports of expenditures.
- 12. Official signing for the applicant organization.
- 13. Signature of Proposed Investigator and date.
- 14. Signature of person named in item 12 and date.

## 2. Project Abstract, Performance site and Key Personnel (Page 2):

Abstract: On a single page, describe precisely and clearly the nature, objective, methods of procedure, and significance of the proposed research project, and how it relates to the goal of providing a better understanding of scleroderma and/or improving scleroderma treatments (limit 500 words). Performance Site: Give complete address of site at which the proposed research will take place. Key Personnel: List all investigators, sponsors and consultants.

## 3. Lay Person Summary (Page 3)

Provide a 200-word summary of the project in terms suitable for presentation to lay persons.

# 4. Budget: Use National Scleroderma Foundation Budget Forms for 1st and each subsequent year(s). Pages 4–6

For the New Investigator Grant, the principal and/or co-investigator salaries are capped at no more than a combined total of \$25,000 per year including fringe benefits.

On the Established Investigator Grant, the principal and/or co-investigator salaries and any key personnel are capped at no more than a combined total of \$50,000 per year including fringe benefits. Travel costs are limited to 2,000/year for the PI to attend national or international scientific meetings.

The National Scleroderma Foundation Research Funding Program allows eight percent of proposal budgets to be allocated towards overhead. Not allowed are construction or renovation costs; purchase of major capital equipment, including computers; office equipment or furniture; tuition fees; journal subscriptions, dues or memberships; equipment service contracts, salaries for administrative personnel; or salaries for clinical trainees. Up to \$5,000 per year may be used to purchase capital equipment for New Investigator Awards only.

- a. Include names, titles, time/percentage effort of all participants, requested salaries and fringe benefits, and total amount required.
- b. Include a written budget justification for all budget categories on the Budget Justification Page.
- c. If the proposed research project involves using a registry, applicant must confirm access with registry administrators before applying to ensure they can accommodate the needs of the study. Please ensure any related costs are included in the budget. (Please attach confirmation letter in the appendix)

## 5. Resources (Page 7):

Describe laboratory, clinical, animal, computer, office and other resources available and major equipment.

# 6. Biosketch of Principal Investigators and Co-investigators:

Use the current NIH biographical sketch format and guidelines. The Biographical Sketch provides information used by reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. A biographical sketch is required for all key personnel.

## 7. Other Support:

List other support received by Principal and Co-Investigators for any projects (include yearly and total budget and duration of any grants). In a paragraph, describe each current or pending grant and whether it has scientific or budgetary overlap with the present proposal. Include information on the following grants:

- a. Current.
- b. Pending.

# 8. Sponsor Letter and Professional Reference Letters (required for New Investigators Awards only) and Letters of Agreement from Co-Investigators:

All New Investigators Award applicants must have a letter of support from a more senior investigator (sponsor) or administrative entity (e.g., Department Chairman) that assures that additional funds will be provided to cover the PI's salary or supplies to conduct the project not covered by the National Scleroderma Foundation award.

Professional reference letters: should be limited to no more than three per investigator.

Letters of agreement from all co-investigators should be included in application.

# 9. Introduction to Revised Application (Limit two pages).

For revised/resubmitted applications, provide no more than two pages of specific responses to previous revision or critiques.

## 10. Research Plan (10 pages): Section A-D is limited to 10 pages.

Begin on a separate page; single-spaced, 11 point or larger typeface, .5 or greater margins. Include the following:

- a. Specific Aims: List the broad, long-term objectives and what the specific research proposed in this application is intended to accomplish, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, or develop new technology.
- b. Background and Significance: Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. One and a half pages are recommended.
- c. Preliminary Studies: Use this section to provide an account of the principal investigator's preliminary studies pertinent to the application information that will also help to establish the experience and competence of the investigator to pursue the proposed project.
  - Peer review committees generally view preliminary data as an essential part of a research grant application. Preliminary data often aids the reviewers in assessing the likelihood of the success of the proposed project.
- d. Research Design and Methods: Describe the research design and the procedures to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as the data sharing plan as appropriate. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or timetable for the project. Point out any procedures, situation, or materials that may be hazardous to personnel and the precautions to be exercised.

Although no specific number of pages is recommended for the Research Design and Methods section, the total for Items (a)–(d) may not exceed 10 pages, including all tables and figures.

- e. Relevance to finding a cure for scleroderma: Describe, <u>in layman's terms</u>, how the proposed studies are related to finding a cure for scleroderma. (Maximum 2 pages)
  - What is the main goal of your research?
  - How will this research benefit people living with scleroderma?
  - · Have people living with scleroderma been involved in shaping your research questions? If so, how?
  - How could your findings lead to new treatments, interventions, or quality-of-life improvements for scleroderma patients?

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- f. Human Subjects: Describe the source of materials, potential risks to the subjects, adequacy of protection against risks, potential benefits of the proposed research to the subjects and others, and the importance of the knowledge to be gained. Include a justification of the number of subjects to be enrolled or number of human cells/tissues to be collected/used. (no page limitation).
- g. Vertebrate Animals: Describe the species that will be used, procedures, number of animals/group with justification for the number, justification of animal use, description of procedures to minimize discomfort, and methods of euthanasia.
- h. Literature Cited: List all references. Each reference must include the title, names of all authors, book or journal, volume number, page numbers, and year of publication. The reference should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.
- i. Consortium/Contractual Arrangements: Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee.
- j. Consultants: Attach appropriate letters here from all individuals confirming their roles in the project. Do not place these letters in the Appendix.
- k. Letters of agreement from all co-investigators.

# 11. Appendix: Include all appendix material in one PDF file. Identify each item with the name of the principal investigator. Do not intermingle appendix materials with the application.

Applications may include the following materials in the appendix:

- Up to three publications, manuscripts (accepted for publication), abstracts, patents, or other printed materials directly relevant to this project may be included. Manuscripts submitted for publication should not be included.
- 2) Surveys, questionnaires, data collection instruments, and clinical protocols.
- 3) Color images provided that a copy (may be reduced in size) is also included within the 10-page limit of Items (a)–(d) of the research plan. No photographs or color images may be included in the appendix that are not also represented within the Research Plan.
- 4) If you are using samples or data from a registry, please attach confirmation letter.

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