

**SCLERODERMA  
FAMILY REGISTRY  
AND DNA  
REPOSITORY**

SUMMARY AND  
APPLICATION  
INSTRUCTIONS

## **Application for Data or Materials from the Scleroderma Family Registry and DNA Repository (SFRDR)**

### Summary for Applicant Investigators

These are the application instructions and forms for an investigator to use in obtaining data or materials from the Scleroderma Family Registry and DNA Repository (hereinafter referred to as SFRDR). The SFRDR is the collected data and materials from single case and multi case families with systemic sclerosis (SSc). While most pedigrees are simplex, some are multiplex with two or more family members with SSc. The purpose in constructing the SFRDR is to build a resource which will accelerate discovery of the genes which contribute to disease susceptibility or modify disease severity. The application procedure is meant to be relatively simple. All concerned with building this resource hope that investigators will find that the data are easily accessible and that the materials are useful for their work. The construction of the SFRDR has been made possible by funding from the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) of the National Institutes of Health (NIH).

The materials and information will be provided to applicant investigators upon approval of their application by the Scientific Advisory Committee. This summary and the accompanying instructions and forms are meant to be a guide for applicant investigators and to facilitate their applications.

Applications must be accompanied by a copy of the IRB approval letter or a letter of waiver from review of the project for de-identified samples or data.

The Advisory Committee of the SFRDR generally reviews applications within six to eight weeks of receipt. Those applications approved outright will be forwarded to officials at the National Institute of Arthritis and Musculoskeletal and Skin Diseases for approval. Successful applicants are referred to as Approved Users of the SFRDR.

Financing for the SFRDR has been provided through NIAMS. There is no part of the existing budget which provides funds for disbursing the materials and information that constitute this resource. Approved investigators are expected to cover the cost of shipping materials. We also hope that investigators would be committed to performing important research, to publishing their results, and to supplying any data collected on pedigree members in a way that can be made part of the SFRDR database.

Investigators are encouraged to make their applications as concise as possible. Suggested maximum page limits are presented. There is no minimum page requirement. Investigators should explain their proposal research as efficiently as possible, both to conserve the time and trouble needed to prepare an application and to reduce the burden of material to be reviewed. To make the process as efficient as possible the Face Page, Abstract Page, Table of Contents, Biographical Sketch, Other Support, Resources, and Continuation Pages are all modeled on the standard forms of the PHS 398 (Rev. 5/95) application package published by the Public Health Service.

The criteria for approving applications from investigators include scientific excellence and competence of the proposal; the experience and training of the investigator (especially with regard to the methodology needed to perform the project proposed); the availability of sufficient resources to perform the proposed study; and the commitment of the investigator and his or her institution to fulfill the conditions of the Letter of Understanding, required of applicants. Also, for applications requesting DNA, serum or plasma, the efficient use of these materials, the potential scientific yield of the proposal and the other applications approved or pending will all be considered.

Please note that all materials described above are provided with NO ACCOMPANYING PERSONAL IDENTIFIERS. Therefore, it will not be possible for applicant investigators to contact participants.

Also, we hope that applicant investigators and their colleagues will introduce us to subjects who are multiplex for scleroderma. We appreciate any referrals of pedigrees for possible inclusion in the SFRDR. To introduce us to multiplex pedigrees please call Registry staffers at 800-736-6864. For more information see our web page at <http://www.sclerodermaregistry.org> and send e-mail via the web page.

For questions about the application procedures or the status of an application, please contact one of the following:

Marilyn Perry	713-500-7162	<a href="mailto:Marilyn.Perry@uth.tmc.edu">Marilyn.Perry@uth.tmc.edu</a>
Victoria Griffin	713-500-7196	<a href="mailto:Victoria.Griffin@uth.tmc.edu">Victoria.Griffin@uth.tmc.edu</a>
Maureen D. Mayes, MD, MPH	713-500-7935	<a href="mailto:Maureen.D.Mayes@uth.tmc.edu">Maureen.D.Mayes@uth.tmc.edu</a>

Our address: Scleroderma Family Registry and DNA Repository  
University of Texas - Houston Medical School  
6431 Fannin, MSB 5.270  
Houston, TX 77030  
Facsimile: 713-500-0723

You may find other useful information on our Home Page which may be found at <http://www.sclerodermaregistry.org>.

We look forward to your application or inquiry.

#### ACKNOWLEDGEMENTS

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The contributions of the following individuals are gratefully acknowledged: John Harley, MD, PhD, and the staff of the Lupus Multiplex Registry and Repository; Susana Serrate-Sztejn, MD; Peter Gregersen, MD; Marvin Fritzler, MD, PhD; Frank C Arnett, MD, Marilyn Perry, Victoria Griffin, and Leigh Anne Werner.

Maureen D. Mayes, M.D., M.P.H.

# SCLERODERMA FAMILY REGISTRY AND DNA REPOSITORY

## APPLICATION FORMS

Face Page  
Abstract, Performance Sites and Key Personnel  
Table of Contents and List Appendices  
Sample Request Form  
Letter of Understanding  
Biographical Sketch(es) for Key Personnel  
Other Support  
Resources

No specific forms are provided for the following items:  
Specific Aims and Experimental Plan  
Letters of Collaboration from Key Personnel  
Literature References  
Other Issues

## APPLICATION INSTRUCTIONS

### Scleroderma Registry and DNA Repository

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*No specific forms are provided for the following items:*

- Specific Aims and Experimental Plan
- Letters of collaboration from key personnel
- Literature References
- Other Issues (if necessary)

#### **Face Page:**

Self-explanatory

#### **Abstract, Performance Sites and Key Personnel:**

Summarize the project(s) you propose and identify the materials or data that you hope to be provided. Key personnel include the Applicant Investigator and any collaborator or colleague whose participation is critical to the success of the project.

#### **Table of Contents and List of Appendices:**

Self-explanatory

#### **Sample Request Form:**

Self-explanatory, refer to PHS Form 398 for any clarification, if needed.

#### **Letter of Understanding:**

Self-explanatory. Signatures of the Applicant Investigator and the Responsible Institutional Official are required.

#### **Biographical Sketch(es) for Key Personnel:**

Self-explanatory. Please particularly provide literature references from the Key Personnel that document experience and competence to perform the proposed project.

**Other Support, Resources:**

The application must establish that the financial and physical resources needed to perform the project are available to the applicant. Some applicants may choose to submit the Other Support and the Resources pages used in PHS grant applications.

**Specific Aims, and Experimental Plan (<5 pages):**

In the Specific Aims please summarize what you intend to accomplish with the materials being provided. Please use less than one page.

**Letters of Collaboration from Key Personnel:**

Please provide a separate letter from each of the Key Personnel (not including the Applicant Investigator) which describes their availability, contribution and commitment to the project.

**Literature References (<2 pages):**

Please provide literature citations with complete author lists and full titles. Please do not exceed two pages.

**Other Instructions:**

**Preparation:** Do not use type smaller than 12 characters per inch. Leave a ½ inch margin on sides, top and bottom. Please number pages sequentially from the beginning to the end.

**Appendices:** These are optional and should only be provided if they are important to the evaluation. We hope that most applicants will choose not to submit appendices. In any case, no more than four published manuscripts or other materials are permitted to be submitted as appendices.

**Submission:** Submit an original and five copies. Package appendices separately. Provide four sets of appendices.

**Resubmission:** If an applicant is rejected or returned with issues left to be resolved or questions to be answered, then the applicant may choose to resubmit the proposal. This may be accomplished in three ways. The applicant may change the title and submit a new proposal. The applicant may revise the text, may provide a letter addressing the outstanding issues (not to exceed three pages), or both. If the text is revised, please identify the changes made. This is usually done with markings in the margin, italics or underlining.

**Supplemental Applications:** An applicant may wish to expand the scope of their research or apply for additional data or materials. When only minor changes are required in the text, then identifying the changes in the text and submitting the revised original application with an introductory letter would be the most efficient choice.

Applicants are requested to acknowledge the Scleroderma family Registry and DNA Repository in published reports of their research and to submit reprints of their publications.

<b>Scleroderma Registry and DNA Repository</b>	<b>LEAVE BLANK-FOR SFRDR USE ONLY</b>		
	Type	Activity	Number
<b>APPLICATION FOR DATA OR MATERIALS</b>	Advisory Committee		Formerly
	SFRDR NIAMS	Date Received	
1. TITLE OF PROJECT (Do not exceed 56 characters, including spaces and punctuation.)			
2. APPLICANT REQUESTS ACCESS TO DATABASE OR MATERIALS, AS INDICATED:	DATABASE	<input type="checkbox"/> NO	<input type="checkbox"/> YES
	PLASMA	<input type="checkbox"/> NO	<input type="checkbox"/> 0.1ml <input type="checkbox"/> 0.4ml
	SERUM	<input type="checkbox"/> NO	<input type="checkbox"/> 0.1ml <input type="checkbox"/> 0.2ml
	DNA	<input type="checkbox"/> .NO	<input type="checkbox"/> YES Amount
<b>3. APPLICANT INVESTIGATOR</b>			
3a. NAME (Last, first, middle)	3b. DEGREE(S)		
3c. POSITION TITLE	3d. MAILING ADDRESS (Street, city, state, zip code)		
	E-MAIL ADDRESS		
3e. DEPARTMENT, SERVICE, LABORATORY OR EQUIVALENT	3f. MAJOR SUBDIVISION		
3g. TELEPHONE AND FAX (Area code, number and extension)			
4. APPLICANT ORGANIZATION Name: Address:	5. TYPE OR ORGANIZATION Public: <input type="checkbox"/> Federal <input type="checkbox"/> State <input type="checkbox"/> Local Private: <input type="checkbox"/> Private Nonprofit For Profit: <input type="checkbox"/> General <input type="checkbox"/> Small Business		
SIGNATURE OF AI NAMED IN 3a. (In ink. "Per" signature not acceptable.)	DATE		

Principal Investigator/Program Director (Last,first,middle): \_\_\_\_\_

**ABSTRACT DESCRIPTION:** State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Describe concisely the research design and methods for achieving these goals. Avoid summaries of past accomplishments and the use of the first person. This abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application. If the application is funded, this description, as is, will become public information. Therefore, do not include proprietary/confidential information. **DO NOT EXCEED THE SPACE PROVIDED.**

PERFORMANCE SITE(S) (*organization, city, state*)

**KEY PERSONNEL.** See instructions. *Use continuation pages as needed* to provide the required information in the format shown below. Start with Principal Investigator. List all other key personnel in alphabetical order, last name first.

Name	Organization	Role on Project
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Type the name of the applicant investigator at the top of each printed page and each continuation page.  
(For type specifications, see instructions.)

## APPLICATION TO THE SCLERODERMA REGISTRY AND DNA REPOSITORY

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Other Biographical Sketches (Not to exceed two pages for each).....	___
Other Support.....	___
Resources.....	___

#### Research Plan

Introduction to Revised or Supplemental Application (Not to exceed 3 pages).....	___
a. Specific Aims.....	___
b. Preliminary Studies/Progress Report.(items a-c: not to exceed 5 pages*).....	___
c. Research Design and Methods.....	___
d. Other Issues (For-profit financial considerations, human subjects, B cell lines, etc.).....	___
e. Letters of Collaboration from Key Personnel.....	___
f. Literature Cited.....	___

\*Type density and type size of the entire application must conform to limits provided in the instructions.

Check if  
Appendix is  
Included

Appendix (Four collated sets. No page numbering necessary for Appendix.)

Number of publications and manuscripts accepted or submitted for publication (not to exceed 4)

Other items (list):

**SAMPLE REQUEST FORM**

1. Name of Investigator: \_\_\_\_\_

2. Title/Institution: \_\_\_\_\_

3. Mailing Address: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

4. Shipping Address: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

5. Office Phone: \_\_\_\_\_ Lab Phone: \_\_\_\_\_

6. E-mail Address: \_\_\_\_\_

7. Person responsible (with contact information) for receiving the samples (if different from the Investigator and information above):

Name: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

Phone: \_\_\_\_\_ FAX: \_\_\_\_\_ E-mail: \_\_\_\_\_

**TYPE OF MATERIALS REQUESTED:**

Database Format: Microsoft Excel \_\_\_\_\_ ASCII Text File \_\_\_\_\_

DNA<sup>1</sup>       No       Yes      Amount \_\_\_\_\_

Serum       No       0.1 ml       0.2 ml

Plasma       No       0.1 ml       0.4 ml

<sup>1</sup>DNA – Range of amounts available are 10 ng to 1.0 mcg

Special Requests if necessary (use continuation page): \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

**LETTER OF UNDERSTANDING**

From the Applicant Investigator and Institution to the  
Scleroderma Family Registry and DNA Repository

Name of Investigator:

Name of Institution:

Institutional Address:

Institution's OHRP Federal-wide Assurance No:

Institution's IRB Registration No:

I (the Investigator named above) and my Institution (named above) hereby apply to be provided materials and/or data from the Scleroderma Family Registry and DNA Repository (SFRDR). We (meaning the Investigator and Institution named above) agree to the terms set below:

1. Materials and/or data obtained through this application process cannot be shared with any other outside investigators or research groups without specific permission from SFRDR. These materials may not be transferred to any commercial entity; applicants may not act as contractors for a commercial entity to analyze these materials; nor may applicants exploit this material for commercial gain, either directly or indirectly, without the participation and written agreement of SFRDR.
2. If access to this material or data makes a contribution to a publication or scientific presentation, the recipient must specifically acknowledge the contribution of SFRDR.
3. If genetic mapping data are generating using SFRDR samples, results must be made available to SFRDR within a reasonable period, but not more than one year after publication results. It is the intent of SFRDR to maintain a genetic database on SFRDR families which will be available to the scientific community.

\_\_\_\_\_  
Signature of Applicant Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Applicant Investigator

\_\_\_\_\_  
Signature of Responsible Institutional Official

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Responsible Institutional Official and Title

Principal Investigator/Program Director (Last,first,middle): \_\_\_\_\_

### OTHER SUPPORT

Provide active support for all key personnel. **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.** Training awards, prizes, or gifts do not need to be included.

Information on other support should be provided in the *format* shown below, using continuation pages as necessary. **Include the principal investigator's name at the top and number consecutively with the rest of the application.** The sample below is intended to provide guidance regarding the type and extent of information requested. Refer to the specific instructions in Section I. For information pertaining to the use of and policy for other support, see "Policy and Additional Guidance."

#### Format

#### NAME OF INDIVIDUAL

#### ACTIVE/PENDING

Project Number (Principal Investigator) Source Title of Project ( <i>or Subproject</i> )	Dates of Approved/Proposed Project Annual Direct Costs	Percent Effort
The major goals of this project are...		

#### OVERLAP (*summarized for each individual*)

Principal Investigator/Program Director (Last,first,middle): \_\_\_\_\_

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## RESOURCES

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**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.

Laboratory:

Clinical:

Animal:

Computer:

Office:

Other:

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