FOUNDATION FOR
SARCOIDOSIS RESEARCH

SARCOIDOSIS
ADVANCED
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Foundation for Sarcoidosis Research Patient Registry Data Application and Confidentiality-Usage Agreement

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Record-level data from the Foundation for Sarcoidosis Patient Registry (FSR-S.A.R.C.) must be approved by the FSR-S.A.R.C. Patient Registry Committee. To uniformly address the requests and ensure that we meet privacy standards, FSR has developed a Data Application and Confidentiality-Usage Agreement, which includes our data access and publication policy. We anticipate that the review process for data requests will take approximately four to eight weeks after receipt of a complete data application. If a data request represents a significant time commitment to fulfill, we will advise you of our proposed timeline and any potential costs to address your request.

The guidelines to establish the process for investigators to access registry data were reviewed and approved by FSR's Patient Registry Committee. Before FSR Patient Registry data can be released, completion of this application and signed Confidentiality-Usage Agreement must be sent to the Foundation (datarequests@stopsarcoidosis.org).

Requirements for approved data requests:

1. The FSR must be acknowledged for oral or written release/use of the data. All manuscripts must include the following acknowledgement: ""The authors would like to thank the Foundation for Sarcoidosis Research for the use of FSR S.A.R.C. Patient Registry data to conduct this study."

2. Progress reports will be solicited on an annual basis. Researchers are required to report all posters, presentations, abstracts, and manuscripts using registry data.

3. Three years after data is sent the FSR will consider the project to be complete unless other requests have been approved. Researchers must either destroy the data files and any copies of the data files and provide written confirmation of the completion of the project to the Foundation, or provide sufficient justification for continuing the project.

4. Supply the FSR at least 30 days prior to proposed submission of publications, or other forms of public disclosure of the data and seven days prior to abstract submission.

5. The FSR Patient Registry Committee will review for approval (with comments, suggestions) or disapproval, each request. The requester must abide by the terms and conditions outlined in the signature page of the Data Application and Confidentiality-Usage Agreement.

PART I: DATA APPLICATION REQUIREMENTS - All data requests must be submitted in writing, noting:

A. Name, title, address, phone, and e-mail of all persons who will be accessing the FSR Patient Registry data as outlined in the research plan.
B. All other collaborators (name, title, institution) on the project, and please describe their role and whether they will have access to the FSR patient registry data. For further clarification, the primary investigator ("PI") shall be an employee of the same institution as the person who will be receiving the FSR patient registry data and who will be performing the data analysis. The FSR patient registry data cannot be shared outside of this institution. At most institutions, medical fellows cannot serve as PIs. If PI desires to share access to the FSR patient registry data with another person(s) who is/are employed with another employer, PI shall notify FSR so FSR may contact them to receive all necessary paperwork, including the Confidentiality-Usage Agreement.
C. Project name, sponsor(s) (if relevant) and IRB approval.
D. The estimated start and end date of the project.
E. Purpose of data request and/or potential use of the data.
F. Research question, hypothesis, objectives, research design, study cohort definition, method of analysis, and sources of bias (1-3 pages).
G. Data variables required from registry questionnaire – please see survey questionnaire to determine there, and refer to question numbers and description in your request.

PART II. Confidentiality-Usage Agreement

1. Patient Confidentiality

Patient confidentiality is protected. FSR releases non-identifiable data for general data requests. Only when imperative for validity of the research project, identifiable data, such as zip code or birth date, may be released in compliance with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) for confidentiality. This Data Application and Confidentiality-Usage Agreement must be completed before these data can be released.

2. Data Usage

FSR promotes the responsible use of the data for well-defined questions. The review process established for all data requests has yielded constructive feedback to investigators ensuring that the research questions are focused, the research is feasible to be conducted with the data available in the FSR S.A.R.C. Registry, the variables of interest are well-defined, and the limitations of the data within the FSR S.A.R.C. Registry, are recognized. The FSR website (www.stopsarcoidosis.org) links to a copy of the FSR S.A.R.C. Registry data collection form illustrating the variables that may be pertinent to your research.

You are encouraged to submit an abstract describing your findings to the annual WASOG Congress. Completion of a manuscript for submission to a peer-reviewed journal within 2-3 years of your receipt of the data should be a goal. If other investigators apply to the FSR for data to pursue similar analyses, they may be granted access as well based on the outcome of the review process. It is in your best interest and in the interest of the sarcoidosis community that you complete your analyses and interpretation of the data as quickly as possible. If you wish to expand upon the scope of work regarding this project or would like to perform related analyses that require additional data, please email your request to datarequests@stopsarcoidosis.org

3. Publication Policy

The Patient Registry Committee must be consulted on any publications resulting from use of the requested data. This will help assure that the interpretations and conclusions of the authors are accurate and consistent with the scientific objectives initially stated in the proposal. It is helpful to specify all proposed collaborators/co-authors at the time of your data request. When abstracts, exhibits, invited papers or manuscripts are prepared using the FSR S.A.R.C. Registry data, the work must include the following acknowledgement: "*The authors would like to thank the Foundation for Sarcoidosis Research for the use of FSR S.A.R.C. Patient Registry data to conduct this study.*" FSR requires that no individually identifiable information from the FSR S.A.R.C. Patient Registry shall be included in publications, and other written products based on the data request. Data must be presented in the aggregate. All tables generated from registry data should include a patient count of five or more in each cell.

FSR recognizes that journals are increasingly shifting to transparency of data presented in their publications and we acknowledge that journals prefer to have data shared and stored in a repository available to other researchers.

Though this is a preference for most journals, we ask that you please include the below statement when submitting a manuscript as FSR is committed to data security and the confidentiality of patients who voluntarily provide data to the FSR S.A.R.C. Registry: *"Data is available upon request through the FSR S.A.R.C. Registry Committee. You can contact the committee at datarequests@stopsarcoidosis.org. Restrictions on access to data are to ensure patient privacy for all persons in the FSR S.A.R.C. Registry."*

Prior to the submission of abstracts, poster presentations, or manuscripts a copy should be sent to datarequests@stopsarcoidosis.org for review by FSR Patient Registry Committee members. We request 30 days for manuscripts and seven days for abstracts. In addition, once the abstract or manuscript are accepted by a scientific organization, one copy of said paper, or a suitable description of the exhibit, shall be forwarded to the FSR on notice of such acceptance, together with the name of the publication or the organization accepting it, and the time and place of the scientific meeting.

4. Commercial Access Policy

Data from the FSR Patient Registry is to be used for valid scientific research that is intended for publication in a peer-reviewed journal. Information from the registry may not be used or further disclosed to direct marketing or sales, or for any purpose that has not been approved by the FSR Patient Registry Committee. Commercial entities may submit a Patient Registry Data Application to be reviewed by the FSR Patient Registry Committee. Data subsets will not be released directly to such applicants; FSR

or an FSR approved third party must be contracted for data analysis. FSR and/or affiliated parties must be compensated for data analysis, details of which will be specified in a subsequent agreement.

CONFIDENTIALITY STATEMENT:

It is the policy of the FSR to protect patient information from unauthorized access or use at all times and to assure that this information will only be utilized, transferred, and/or stored in sanctioned and approved ways to provide the strictest confidentiality of the patients in our national Patient Registry database. This obligation continues after a patient has deceased or an investigator ceases a relationship with the FSR. Patient identifiers (i.e., zip code) and center identifiers will not be released by the FSR unless imperative to the project and approved by the Patient Registry Committee, and the researcher's institution enters into an Information Use Agreement with the FSR to ensure confidentiality safeguards, are in place to address HIPAA. No data should be used for marketing purposes.

The data will be released to you with the agreement that you will be a responsible user of the FSR Patient Registry data specific to your request, and that you will only use the data for the exact purpose for which you have requested. Further, you agree not to disclose any information without the written permission of the FSR. Upon the completion of data analyses, you must destroy the original and any duplicate data files.

FSR must be notified at least 30 days prior to submission (seven days for abstracts) and receive copies of any proposed submission of abstracts, publications or other form of public disclosure of the data. This is to ensure adequate time for review in order to verify that the interpretation and conclusions of the authors are accurate and consistent with the scientific objectives initially stated in the proposal.

The FSR must be acknowledged for oral or written release and use of the data.

ACKNOWLEDGMENT:

The Institution agrees to the terms of this Data Application and Confidentiality-Usage Agreement causes this Confidentiality Agreement to be executed as of the date of the Institution's signature ("Effective Date") by an authorized representative.-

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INSTITUTION:

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AUTHORIZED REPRESENTATIVE NAME/TITLE:

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SIGNATURE: DATE:

READ AND AGREED: I, the principal investigator, have read and agree to abide by the standards set forth in this DATA APPLICATION AND CONFIDENTIALITY-USAGE AGREEMENT from the Foundation for Sarcoidosis Research, but not as a formal party.

_____

NAME/TITLE:

_____

EMAIL: PHONE:

_____

ADDRESS: (Street) (City) (State/Zip Code) (Country)

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SIGNATURE: DATE:

PLEASE SUBMIT IN PDF FORMAT TO datarequests@stopsarcoidosis.org