CYSTIC FIBROSIS FOUNDATION
ADDING TOMORROWS

TO: Investigators Requesting Data from the Cystic Fibrosis Foundation Patient Registry

FROM: Albert Faro, MD, Senior Vice President and Chief Medical Officer

SUBJECT: CF Foundation Patient Registry Research Data Application and Confidentiality Agreement

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Requests from investigators at academic institutions for access to record-level data from the Cystic Fibrosis Foundation Patient Registry (CFFPR) must be reviewed and approved by the CF Foundation Patient Registry/Comparative Effectiveness Research (CER) Committee. To uniformly address requests and ensure that we meet privacy standards, the CF Foundation has developed a Data Application and Confidentiality Agreement, which includes our data access and publication policy. We anticipate that the review process for data requests will take at least three to six months after receipt of a complete data application, which includes the application, proof of Institutional Review Board (IRB) submission for your proposed project, a signed Confidentiality Agreement (final page of this document), and variable list. 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. Note: Requests from Industry have a separate process. Please email datarequests@cff.org for information about this process.

Guidelines to establish the process for investigators to access CFFPR data were reviewed and approved by the CF Foundation's Registry/CER Committee. Our highest priority is ensuring that CFFPR data voluntarily provided by individuals with cystic fibrosis and their families are maintained in a confidential manner and used to further our understanding of CF, its care, and treatments. Before releasing data, we must be assured that the following issues are addressed. The CF Foundation reserves the right to deny access to CFFPR data.

1. Patient confidentiality is protected.
The CF Foundation releases non-identifiable data for general data requests. Only when imperative for validity of the research project, protected health information (PHI), 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. In these cases, it will also be necessary to have a signed Information Use Agreement before data can be released. The Information Use Agreement is a separate document requiring signatures from authorized representatives at the requestor's institution and the CF Foundation.

If your proposed research is funded or may be funded by the National Institutes of Health (NIH) in whole, or in part, please indicate such in your data request. If, at any time during your research, your project becomes funded by the NIH, you must notify the CF Foundation immediately. We will need to coordinate with your NIH program officer regarding the NIH Data Sharing Policy and its applicability to CFFPR data requests.

2. Promote 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 CFFPR, the variables of interest are well-defined, and the limitations of the data within the CFFPR are recognized. The linked CFFPR data collection form lists the variables that may be pertinent to your research. It is also important to define the specific years of data needed for the research.

Data for a given year are available approximately 12-18 months after the end of that calendar year (for example, 2020 data will become available in mid-2022).

If other investigators apply to the CF Foundation for data to pursue similar analyses, they may also be granted access, based on the outcome of the review process.

It is in your best interest and in the interest of the CF community that you complete your analyses and interpretation of the data as quickly as possible. Completion of the project with submission of your findings to a peer-reviewed journal within **three years** of receipt of the data should be your goal. **If you have had data for three years without submission to a journal, we will notify you that we are closing your application and you will need to request a new data cut.** We will give you an opportunity to justify a length of time over three years, but we reserve the right to close your project and request return and destruction of CFFPR data.

We recognize that to conduct analysis using the CFFPR takes time and effort to understand the data and apply statistical techniques to ensure valid results. Therefore, the CF Foundation does not provide data in situations where the investigators will not have sufficient time to work on the project, such as students looking to complete a project within a semester-long class.

We encourage submissions from applicants in the early stages of their careers, and we require evidence of institutional support and mentorship from people who understand both CF and the CF Foundation Patient Registry data. Please clearly indicate in your proposal if your project is intended to fulfill requirements for a graduate degree or post-graduate program, such as a fellowship.

The CF Foundation will follow up with requestors annually after data are sent for three years or until project completion. The follow-up report will request a progress update on work done on the project; any conference abstracts, presentations, or manuscripts; and lay summaries to be written for each published manuscript. Researchers must either destroy the data files and any copies of the data files and provide written confirmation of destruction of the data and completion of the project to the CF Foundation.

If after you receive your data, you recognize the need to request a small number of additional variables or additional years of data to address the research objectives of your original request, please email datarequests@cff.org with your rationale for the request and the specific additional variables/years of data requested.

If you wish to expand upon the initial scope of work for an existing approved project, please email your request to datarequests@cff.org. We will determine if the proposed work is within the scope originally proposed or requires a new application.

3. Dissemination Policy

You are encouraged to submit an abstract describing your findings to the annual North American CF Conference or other professional conferences.

Prior to the submission of abstracts, poster presentations, and manuscripts, a copy should be sent to datarequests@cff.org for review and approval by the CF Foundation and/or members of the Patient Registry/CER Committee. We request seven days for review of abstracts or poster presentations, and 30 days to review manuscripts. In addition, once the manuscript is accepted by a scientific organization, a copy of said paper shall be forwarded to datarequests@cff.org on notice of such acceptance, along with the name of the publication.

When abstracts, exhibits, invited papers, or manuscripts are prepared using CFFPR data, the work must include the following acknowledgment:

> *The authors would like to thank the Cystic Fibrosis Foundation for the use of CF Foundation Patient Registry data to conduct this study. Additionally, we would like to thank the patients, care providers, and clinic coordinators at CF centers throughout the United States for their contributions to the CF Foundation Patient Registry*

The CF Foundation requires that no individually identifiable information from the CF Foundation 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 and any values less than 5 should be represented as "<5."

The CF Foundation recognizes that journals are increasingly shifting to transparency of data presented in their publications. 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, please include the below statement when submitting a manuscript, as the CF Foundation is committed to data security and the confidentiality of patients who voluntarily provide data to the CFFPR. The CF Foundation maintains copies of all data sets sent to researchers, and if you are audited, we can provide you with the data again.

Suggested data availability language:

> *Data are available upon request through the Cystic Fibrosis Foundation Patient Registry/ Comparative Effectiveness Research Committee. You can contact the committee at datarequests@cff.org. Restrictions on access to data are to ensure patient privacy for all persons in the CF Foundation Patient Registry.*

Additionally, exhibits, invited papers or manuscripts prepared using the CFFPR data should include a reference to the following publication:

> Knapp EA, Fink AK, Goss CH, Sewall A, Ostrenga J, Dowd C, Elbert A, Petren KM, Marshall BC. The Cystic Fibrosis Foundation Patient Registry: Design and Methods of a National Observational Disease Registry. *Annals of the American Thoracic Society*. 2016 13(7):1173-9.

4. Commercial (or Other Unapproved) Access Policy

Data from the CFFPR are 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 other purpose that has not been reviewed and approved by the Patient Registry/ CER Committee**. If your research is or may be funded by the NIH and subject to the NIH Data Sharing Policy, please notify the CF Foundation immediately.

Cystic Fibrosis Foundation Patient Registry Data Application and Confidentiality Agreement

All data requests must be submitted as described below, noting:

- For all members of the project team: Name, title, address, phone, e-mail, role on the project, and whether they need access to CF Foundation Patient Registry data. It is the principal investigator's responsibility to ensure that all team members have reviewed and approve the proposal for submission to the CF Foundation. For further clarification, the primary investigator (PI) should be an employee of the same institution as the person who will be receiving the CF Foundation Patient Registry dataset and performing the analysis. The CF Foundation Patient Registry dataset cannot be shared outside of this institution.
- At most institutions, medical fellows cannot serve as PIs. Please list the fellow's mentor as the PI.
- The Confidentiality Disclosure Agreement (CDA), IRB approval letter, and Information Use Agreement that is applicable when identifiers are requested shall all be executed with the institution where the CF Foundation Patient Registry dataset will be released by the CF Foundation.
- If the PI needs to share their CF Foundation Patient Registry dataset with another person(s) who is/are employed elsewhere, please indicate this on the application in the collaborator identification section. The CF Foundation will contact them regarding all necessary paperwork, including the Confidentiality Disclosure Agreement, the IRB approval letter, and the Information Use Agreement.
- Prior to any team member with access to the dataset changing institutions during the project, the CF Foundation must be notified via datarequests@cff.org. Regulatory documents will need to be updated with the new institution prior to the dataset leaving the original institution.

Data requests must include the following:

1. Electronic submission through the data requests portal: https://www.cff.org/Research/Researcher-Resources/Tools-and-Resources/Data-Requests-Portal/.
2. Project name, sponsor(s) (if relevant), and IRB approval.
3. Purpose of data request and/or potential use of the data.
4. Research question, hypothesis, objectives, research design, study cohort definition, method of analysis, and sources of bias.
5. Specification of year(s) of Registry data requested. Data are available back to 1986 through the two years prior to the request (for example, 2020 data are available starting in 2022). Note: Not all variables were collected back to 1986.
6. Data variables required from Registry questionnaire, including preferred software package for receiving data (for example, SAS or Excel).
7. If your proposal is approved, once all regulatory requirements have been met, you will be provided with a dataset via secure electronic file transfer.
8. Any actual or anticipated funding from the National Institutes of Health.

Data request approval mechanism:

Investigators should submit a proposal, spreadsheet of variables requested, signed confidentiality agreement (last page of this document), and documentation of IRB approval via the data requests portal. Members of the CF Foundation Patient Registry/CER Committee will review each request and provide either approval (with comments/suggestions), a request to revise and resubmit, or disapproval. Requesters who are approved to receive data must abide by the terms and conditions outlined on the signature page of the Data Application and Confidentiality Agreement.

CFFPR DATA APPLICATION AND CONFIDENTIALITY AGREEMENT

CONFIDENTIALITY STATEMENT:

It is the policy of the Cystic Fibrosis Foundation 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 their relationship with the CF Foundation. Patient identifiers (i.e., zip code) and center identifiers will not be released by the CF Foundation unless imperative to the project and approved by the Patient Registry/CER Committee, and the researcher's institution enters into an Information Use Agreement with the CF Foundation 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 CF Foundation 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 CF Foundation. Documentation of IRB approval must be received prior to the release of data. Upon the completion of data analyses, you must destroy the original and any duplicate data files. **Please contact datarequests@cff.org to request the documents to certify data destruction and project completion.**

The CF Foundation 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 CF Foundation must be acknowledged for oral or written release and use of data.

ACKNOWLEDGMENT:

The Institution agrees to the terms of this Data Application and Confidentiality Agreement and causes this Confidentiality Agreement to be executed as of the date of the Institution's signature ("Effective Date") by an authorized representative. **Please address any questions to datarequests@cff.org regarding this agreement.**

INSTITUTION: _____

AUTHORIZED INSTITUTIONAL REPRESENTATIVE NAME AND TITLE:

_____

By: _____ _____

(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 AGREEMENT from the Cystic Fibrosis Foundation, but not as a formal party.

NAME AND TITLE: _____

PROJECT NAME: _____

PROJECT END DATE: _____

PROJECT SPONSOR: _____

IRB REVIEW STATUS: _____

ADDRESS: _____
(Street)

_____
(City) (State/Zip Code) (Country)

TELEPHONE: _____ FAX: _____ E-MAIL: _____

By: _____ _____
(SIGNATURE OF PRIMARY INVESTIGATOR) (DATE)

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