



TO: Investigators Requesting Data and/or Analyses from FND Scientific Registry

FROM: FND Hope

SUBJECT: FND Scientific Registry Data Access Guidelines

Data collection, data analyses or access to record-level data from FND Hope’s FND Scientific Registry must be approved by the FND Hope Scientific Registry Advisory Committee. To uniformly address the requests and ensure that we meet privacy standards, FND Hope has developed a [Research Proposal Form](#) and [Data Access Agreement](#), which must be executed prior to data collection, analyses or access by the investigator. We anticipate that the review process for data requests will take approximately two to four weeks after receipt of a complete research proposal form. 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 the FND Hope Scientific Registry Advisory Committee. Before FND Scientific Registry data can be released, proof of Institutional Review Board (IRB) approval of your proposed project must be sent to research@fndhope.org. Before releasing data, we must also be assured that the following issues are addressed. FND Hope reserves the right to deny access to FND Scientific Registry data.

1. Patient Confidentiality is Protected

FND Hope 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. The [Data Access Agreement](#) must be completed before these data can be released.

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 FND Scientific Registry, the variables of interest are well-defined, and the limitations of the data within FND Scientific Registry are recognized. The existing survey instruments from the FND Scientific Registry are available [here](#). This may give you an idea if the existing data is pertinent for your research.



3. Publication Policy

The FND Hope Scientific Registry Advisory Committee may 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 FND Scientific Registry data, the work must include the following acknowledgement:

The authors would like to thank FND Hope for the use of FND Scientific Registry data to conduct this study.

From time to time, FND Hope may be well suited to co-author a paper along with other researchers. If this may be of interest, please discuss with us.

You are encouraged to submit an abstract describing your findings to FND Hope for inclusion in its newsletter and also to relevant conferences. 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 FND Hope 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 FND community that you complete your analyses and interpretation of the data as quickly as possible.

FND Hope requires that no individually identifiable information from the FND Scientific Registry shall be included in publications and other written products based on the data request. Data must be presented in the aggregate.

FND Hope 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 FND Hope is committed to data security and the confidentiality of patients who voluntarily provide data to the FND Scientific Registry.

Suggested data availability language:

Data is available upon request through the FND Hope Scientific Registry Advisory Committee. You can contact the committee at research@fndhope.org. Restrictions on access to data are to ensure patient privacy for all persons in the FND Scientific Registry.

Prior to the submission of abstracts, poster presentations, or manuscripts a copy should be sent to research@fndhope.org for review by FND Hope Scientific Registry Advisory 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 FND Hope 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. Timeliness and Cost

FND Hope can provide an estimate of costs to access registry data based on the Research Proposal and, possibly, follow-up discussions. FND Hope may reject data requests due to excessive resource requirements e.g., (time, expense). FND Hope will invoice the requestor for payment.

5. Commercial Access Policy

Data from the FND Scientific 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 FND Hope Scientific Registry Advisory Committee.

Commercial entities may submit a Research Proposal Form to be reviewed by the FND Hope Scientific Registry Advisory Committee.