



TO: Investigators Requesting Data and/or Analyses from iCureCeliac®

FROM:

SUBJECT: Celiac Disease Foundation Patient Registry Data Access Guidelines

Data collection, data analyses or access to record-level data from Celiac Disease Foundation's iCureCeliac® Patient Registry must be approved by the CDF Research Committee. To uniformly address the requests and ensure that we meet privacy standards, CDF has developed a Research Proposal Form and Data Access and Confidentiality 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 eight 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 CDF Research Committee. Before iCureCeliac® data can be released, proof of Institutional Review Board (IRB) approval of your proposed project must be sent to CDF (icureceliac@celiac.org). Before releasing data, we must also be assured that the following issues are addressed. CDF reserves the right to deny access to iCureCeliac® data.

1. Patient Confidentiality is Protected

CDF 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, Confidentiality Agreement, and an Information Use 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 iCureCeliac®, the variables of interest are well-defined, and the limitations of the data within iCureCeliac® are recognized. The enclosed copy of iCureCeliac® fields (attached as an excel document) lists the data elements that may be pertinent to your research.

You are encouraged to submit an abstract describing your findings to the annual Celiac Disease Foundation National Conference. 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 CDF 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 celiac disease and gluten sensitive 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 icureceliac@celiac.org.

3. Publication Policy

The CDF Research 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 iCureCeliac® data, the work must include the following acknowledgement:

The authors would like to thank the Celiac Disease Foundation for the use of iCureCeliac® data to conduct this study.

CDF requires that no individually identifiable information from iCureCeliac® 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.

CDF 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, you must include the below statement when submitting a manuscript as CDF is committed to data security and the confidentiality of patients who voluntarily provide data to iCureCeliac®. CDF 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 is available upon request through the CDF Research Committee. You can contact the committee at icureceliac@celiac.org. Restrictions on access to data are to ensure patient privacy for all persons in iCureCeliac®.

Prior to the submission of abstracts, poster presentations, or manuscripts a copy must be sent to icureceliac@celiac.org for review by CDF Research 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 CDF 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

CDF may reject data requests due to excessive resource requirements e.g., (time, expense). CDF may submit an invoice to the requestor to cover costs for data collection and preparation of data subsets or data analyses.

5. Commercial Access Policy

Data from iCureCeliac® 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 CDF Research Committee.

Commercial entities may submit an iCureCeliac® Data Application to be reviewed by the CDF Research Committee.