Data Disclosure Policies and Procedures from the California Neurodegenerative Disease Registry

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California Neurodegenerative Disease Registry
Chronic Disease Surveillance and Research Branch
1631 Alhambra Boulevard, Suite 200
Sacramento, CA 95816

Version 1.1

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I. Introduction

In 2021, California enacted Health and Safety Code (HSC) section 103871 required the California Department of Public Health (CDPH) to collect other neurodegenerative diseases such as Alzheimer's Disease, multiple sclerosis (MS), Huntington's disease, and amyotrophic lateral sclerosis (ALS) until January 2028.

In 2023, HSC 103871 was amended. One of the amendments in subsection (b) added the following words, "…neurodegenerative disease, including, but not limited to, amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease." Subsection (i) was amended to "'neurodegenerative disease' may also include, but need not be limited to, Alzheimer's disease, multiple sclerosis, and Huntington's disease."

The CNDR is a program in the CDPH, Chronic Disease Surveillance and Research Branch (CDSRB). The purpose of this data disclosure policy is to outline the requirements, procedures, and instructions for requesting disclosure of CNDR data. The disclosure of confidential CNDR data to qualified applicants is governed by the following:

HSC section 103871 and 103871.1 including without limitation the provisions relating to confidentiality, security, use, access, disclosure, and publication of CNDR data.

California Information Practices Act, California Civil Code section 1798, et seq., and California Welfare and Institutions Code section 10850.

The Common Rule, also known as the Federal Policy for the Protection of Human Subjects (45 CFR part 46, subpart A) and the terms and conditions of approval by an institutional review board of any human subjects research using CNDR data.

All other federal and state laws or regulations applicable to confidentiality, security, use, access, disclosure, and publication of CNDR data.

The terms and conditions of any agreement entered with CDPH, CDSRB or a recipient of CNDR data that relates to the confidentiality, security, use, access, disclosure, or publication of CNDR data. The standard agreement forms, which are linked throughout this document, incorporate the policies and procedures outlined herein by reference.

If these authorities conflict, the most restrictive requirement shall govern. If you have a question about the applicability or interpretation of these requirements, please contact:

Catrina Taylor, PhD, MSPH
Chief, Surveillance and Research Section
Director, California Neurodegenerative Disease Registry
California Department of Public Health
Phone: 916-731-2500
Email: CNDRHelp@cdph.ca.gov

II. Disclosure of CNDR Data

1. General Guidelines

Pursuant to HSC section 103871 (g), “Except as otherwise provided in this section, all information collected pursuant to this section shall be confidential.” Pursuant to 103871.1 (b), “The department may enter into agreements to furnish confidential information to other states’ neurodegenerative disease registries, federal neurodegenerative disease control agencies, local health officers, or health researchers for the study of neurodegenerative disease. Before confidential information is disclosed to those agencies, officers, researchers, or out-of-state registries, the requesting entity shall agree in writing to maintain the confidentiality of the information, and in the case of researchers, shall also do both of the following:

(1) Obtain approval of their committee for the protection of human subjects established in accordance with Part 46 (commencing with Section 46.101) of Title 45 of the Code of Federal Regulations.

(2) Provide documentation to the department that demonstrates to the department’s satisfaction that the entity has established the procedures and ability to maintain the confidentiality of the information.”

Accordingly, CNDR data may be disclosed to: 1) Persons with a valid scientific interest who are engaged in demographic, epidemiological, or other similar studies related to health who meet qualifications as determined by the department; 2) state neurodegenerative disease registries; 3) federal neurodegenerative disease control agencies; 4) local health officers; or 5) health researchers for the study of neurodegenerative disease. In the case of researchers, disclosure of CNDR data must be requested by an individual, usually a Principal Investigator (PI). As part of the request, the PI must meet all the requirements described in sections 2 and 3 below. All recipients must sign agreements to protect the confidentiality and security of data and to comply with all relevant governing authorities.

Pursuant to HSC 103871.1 (c), only data necessary for the stated purpose of the request may be disclosed. The data may be used only for the approved purpose. Redisclosure of CNDR confidential information by a recipient and/or their institution is not permitted.

2. Disclosure to Other States’ Registries, Federal Control Agencies, and Local Health Officers

As set forth above, CNDR is authorized to enter into agreements to provide CNDR data to other states’ neurodegenerative disease registries, federal neurodegenerative disease control agencies, and local health officers for the study of neurodegenerative disease under HSC 103871.1 (b). The requesting agency must submit an application to CNDR to determine eligibility to receive CNDR data. If granted, the requesting agency must

sign an agreement to maintain the security and confidentiality of CNDR data, among other terms.

a. Application Procedure

The following minimum materials must be submitted to apply and to receive CNDR confidential information:

1. The completed Application for Disclosure of Confidential Neurodegenerative Disease Data, including a signed Statement of Intended Use.
2. A signed CNDR Data Use and Disclosure Agreement, by the head of a state neurodegenerative disease registry, the head federal neurodegenerative disease control agency, or local health officer.
3. List of requesting data variables/elements

CNDR will review the application materials and may request additional information. The requester will be notified in writing once the application is approved by the Director of CNDR or their designee.

b. Renewal and Annual Review

All agreements between CNDR and federal agencies, local agencies, or other registries are valid for one year from the date they are signed. They will be reviewed and renewed on a yearly basis upon the expiration of the agreement. If the agreement is not renewed on time, access to CNDR data may be paused until a new agreement is in place. The Recipient is also required to submit a list of individuals who have accessed CNDR data with the following information: name of the person authorizing access, name, title, address, and organizational affiliation of the persons granted access, dates of access (which may cover a prospective period not to exceed one year), and the specific purpose for which the CNDR data was accessed. Upon the expiration or termination of the Agreement, completion of the CNDR Data Destruction Acknowledgement Form (see Appendix 1) may be required to document the secure destruction of CNDR data, when consistent with the terms of the Agreement and applicable law. Some recipients may have legal obligation to retain data and may not be subjected to this requirement.

3. Disclosure to Researchers

CNDR may enter into agreements to provide CNDR data to researchers for the study of neurodegenerative disease under HSC 103871.1 (b). Researchers applying for CNDR data are required to demonstrate in an application that their research has scientific merit and submit Institutional Review Board (IRB) approval and California Committee for Protection of Human Subjects (CPHS) approval as outlined below.

a. Application Procedure

The following minimum materials must be submitted to apply to receive CNDR confidential information for research purposes:

Note: If multiple institutions are involved in a single project, each Recipient Institution will be required to submit the following.

1. A study protocol of the project (excluding Appendices).
2. Documentation of peer review for scientific merit. Usually, a funding agency award or dissertation committee approval meets this condition. In some cases, this condition may be met by convening a CDPH review committee.
3. Documentation that the research study has been reviewed and approved by the requestors IRB.
4. Documentation that the research study has been reviewed and approved by the CPHS.
5. A copy of the approved CPHS application.
6. A list of requested data items with justifications.
7. A signed CNDR Data Use and Disclosure Agreement, by the PI and an authorized representative of the Recipient Institution.
   See CPHS Section below for details on obtaining a letter of support

CNDR will review the application materials and may request additional information. The PI will be notified in writing once the application is approved by the Director of CNDR or their designee.

b. Obtaining CPHS Approval

All data request applications require documentation of approval by the CPHS in addition to an institutional IRB approval.

- Instructions for submitting an application for CPHS approval can be found at the California Health and Human Services Agency- Committee for the Protection of Human Subjects website.

  CPHS Contact:
  California Health and Human Services Agency
  Committee for the Protection of Human Subjects
  1215 O Street, 11th Floor, Sacramento, CA 95814
  Phone: (916) 955-6265
  Email: cphs@chhs.ca.gov

- The CPHS requires a letter of support from the CNDR, signed by the Director of CNDR or designee. To obtain this letter, researchers will need to submit an abstract of the project along

with the project title, and name and mailing address of the PI, and CNDR staff will provide a signed CPHS Appendix VII (letter of support) for the CPHS review process.

c. Types of Data Release

i. Analytic Files (case listing for analysis):

Research studies requesting datasets containing elements of CNDR confidential information require a defined study design and research protocol. Data must be used for the stated purpose only, not be redisclosed, and be destroyed upon completion of the study.

ii. Patient Personal Identifiers Data for Patient Contact Studies

Cases for approved patient contact studies shall be identified based upon the study's selection criteria. Six months after receiving the case list, researchers shall be required to return information to CNDR on each patient contacted, noting the date of contact and enrollment status (e.g., non-eligibility, not found, no response, or refusal).

CNDR will limit as much as possible the number of patients released for contact studies. Requests for a large number of cases may be approved if there is strong justification. The number of patient records released in a single batch shall be limited to approximately 2,000. If needed, additional records may be released to the researcher provided that information for patients previously contacted is returned to CNDR.

d. Special Requirements for Research Studies Involving Patient Contact

In addition to the requirements set forth above, researchers requesting CNDR data for studies that involve patient contact must comply with the following requirements:

1. The first contact with a patient must be in writing. Specifically, the investigator must send a contact letter to the patient that explains how the patient's name was obtained and why the CNDR was created. A copy of the CNDR Patient Information brochure, available in multiple languages on the California Neurodegenerative Disease Registry website (https://go.cdph.ca.gov/cndr).

2. During the patient recruitment phase of a study, any problems that arise with individual patients, for example hostile refusals, must be promptly reported to CNDR. Any patient who states that he/she does not wish to be contacted again by any researcher must be reported to CNDR in writing.

3. The researcher must notify CNDR if he or she becomes aware of errors or omissions in the CNDR data and any more current information on a patient's vital statistics and current address.
4. The researcher must return the names and contact information to CNDR on each patient contacted, noting: date of contact and enrollment status (e.g., non-eligibility, not found, no response, or refusal).
5. The researcher may not re-contact study subjects for reasons other than the approved study.

e. Redisclosure of CNDR Data by Researchers

Under no circumstances shall a recipient redisclose CNDR confidential information. Pursuant to HSC section 103871.1(f), CNDR confidential information shall not be available for subpoena, shall not be disclosed, discoverable, or compelled to be produced in any civil, criminal, administrative, or other proceeding, and shall not be deemed admissible as evidence in any civil, criminal, administrative, or other tribunal or court for any reason.

f. Access to CNDR Data by PI staff

The Recipient may grant access to the CNDR data to the workforce members of their research team to carry out a specific assignment on behalf of the Recipient, which is directly related to the use for which disclosure was granted. Examples of such persons include, but are not limited to, research assistants, statisticians, information technology specialists, study coordinators, data analysts, etc. Persons having such access must and agree in writing to maintain the confidentiality of the data in accordance with the data use agreement.

g. Renewal of Approvals and Annual Reporting to CNDR Regarding CNDR Data Disclosure

The Recipient is required to submit renewal approval letters from the institutional IRB and CPHS upon expiration of approval letters. The Recipient is also required to submit a list of individuals who have accessed CNDR data with the following information: name of the person authorizing access, name, title, address, and organizational affiliation of the persons granted access, dates of access (which may cover a prospective period not to exceed one year), and the specific purpose for which the CNDR data was accessed. If the study is complete, the Recipient is required to complete the CNDR Data Destruction Acknowledgement Form documenting CNDR data has been destroyed (see Appendix 1).

III. Publications, Reports, and Statistical Compilations

1. General Guidelines

HSC Section 103871.1 requires that reports and statistical compilations based on CNDR confidential information do not in any way identify individuals or individual sources of information.

CNDR and Recipients may release publications and make presentations to the public containing de-identified and non-re-identifiable aggregate data and conclusions drawn from studying CNDR data, including journal articles, summary reports, special analyses, studies and other documents, and presentations to professional organizations, the news media and the public. These publications may contain case counts, rates, and other analyses derived from CNDR incidence and prevalence data. CNDR confidential information collected by and disclosed to recipient consisting of individual cases or individual sources of information shall not be redisclosed. In situations where data re-identification is possible, the California Health and Human Services (CHHS) Data De-Identification Guidelines or standards that are at least as stringent as the CHHS De-Identification Guidelines must be used to determine the appropriate aggregation or masking level of data for release.

Recipients are required to provide an electronic or paper copy of any journal article or other publication arising out of their research using CNDR confidential information to CNDR and the Director of CNDR prior to publication.

2. Acknowledgement and Disclaimer

All publications using CNDR confidential information shall contain the following disclaimer:

> "The collection of neurodegenerative disease incidence and prevalence data used in this study was supported by the California Department of Public Health pursuant to HSC Sections 103871. The ideas and opinions expressed herein are those of the author(s) and do not necessarily reflect the opinions of the State of California, Department of Public Health."

IV. Procedures for Processing Patient Requests for Access to Data

Individuals have the right to access records containing their personal information maintained by CNDR according to HSC Sections 103871.1 (f)(2) and the California Information Practices Act, Civil Code Sections 1798-1798.78. "Personal information" is information that identifies or describes an individual including, but not limited to his or her name, home address, social security number, physical description, or medical history.
CNDR records can only be released to the individual to whom the records pertain or their legal representative. To request your information please complete CDPH form 6236 (Personal Information). To request access to information by parent, guardian, or personal representative please complete CDPH form 6237.

Forms must be submitted to:
California Department of Public Health
Office of Legal Services
1415 L Street, Suite 500
Sacramento, CA 95814

If you have any questions, please contact CNDR at (916) 731-2500, or by email at CNDRhelp@cdph.ca.gov.

Data Destruction Acknowledgment

Principal Investigator's (PI) Name:_____ PI Institution:_____

Project:_____

Project Approval Date:_____

This is to certify that ALL California Neurodegenerative Disease Registry and (CNDR) data in my possession, pertaining to this project, have been destroyed in accordance with International Organization for Standardization (ISO) recommended destruction methods for physical and electronic documents. Destruction means physical destruction of files, documents and/or other records. De-identification of records shall not be considered destruction.

_____

PI Printed Name & Title

_____

PI Signature

_____

Date

1631 Alhambra Boulevard, Suite 200 / Sacramento, CA 95816 / Tel. (916) 731-2500 / Fax. (916) 454-1538