

Data Disclosure Policies and Procedures
from the California Parkinson's Disease Registry

May 2021

California Parkinson's Disease Registry
Chronic Disease Surveillance and Research Branch
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Version 1.0

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I. Introduction

In 2017, Senate Bill (SB) 97 created the Richard Paul Hemann Parkinson's Disease Program and California Health and Safety Code (HSC) Section 103870, requiring health care providers diagnosing or treating Parkinson's disease patients to report each case of Parkinson's disease to California Department of Public Health (CDPH). The California Parkinson's Disease Registry (CPDR) is a program in the State of California, Department of Public Health, 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 CPDR data. The disclosure of confidential CPDR data to qualified applicants is governed by the following:

HSC section 103870 and HSC section 103870.1, including without limitation the provisions relating to confidentiality, security, use, access, disclosure, and publication of CPDR 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 CPDR data.

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

The terms and conditions of any agreement entered with CDPH, CDSRB or a recipient of CPDR data that relates to the confidentiality, security, use, access, disclosure, or publication of CPDR data. The standard agreement forms in the appendices incorporate the policies and procedures set forth 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:

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II. Disclosure of CPDR Data

1. General guidelines

Pursuant to HSC 103870.1 (b), “The department may enter into agreements to furnish confidential information to other states’ Parkinson’s disease registries, federal Parkinson’s disease control agencies, local health officers, or health researchers for the study of Parkinson’s 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, CPDR data may be disclosed through two general categories of eligibility described in more detail below: 1) State, Federal, or local health entities; or 2) researchers for the study of Parkinson’s disease (Disclosure to Research Institutions). Disclosure of CPDR data must be requested by an individual, usually a Principal Investigator (PI), and the institution with which the PI is affiliated. As part of the request, the PI and an authorized representative of the institution must meet all the requirements described below. Data recipients must also comply with all relevant governing authorities.

Pursuant to HSC 103870.1 (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 data by a recipient and/or their institution are not generally permitted. In exceptional cases, redisclosure of CPDR data may be granted and must be approved by CDPH/CDSRB in writing. Under an agreement with the Veteran’s Administration (VA), CPDR may not release information about VA cases to researchers.

2. Disclosure to other states’ registries, federal control agencies, and local health officers

CDSRB may enter into agreements to provide CPDR data to other states’ Parkinson’s disease registries, federal Parkinson’s disease control agencies, and local health officers for the study of Parkinson’s disease under HSC 103870.1 (b). The requesting agency should submit their request to CDSRB to determine eligibility under this subsection. If granted, the requesting agency must indicate their agreement in writing to maintain confidentiality of CPDR data.

3. Disclosure to Research Institutions

CDSRB may enter into agreements to provide CPDR data to health researchers for the study of Parkinson’s disease under HSC 103870.1 (b). Researchers applying for CPDR

data are required to demonstrate that their research has scientific merit, Institutional Review Board (IRB) approval, and documentation of approval by the California Committee for Protection of Human Subjects (CPHS) as outlined below.

a. Application procedure

The following minimum materials must be submitted to CDSRB for data disclosures for research:

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. Approved CPHS application and documentation that the research study has been reviewed and approved by the requestor's IRB and by CPHS.
4. Confidentiality Agreement for Use and Disclosure of CPDR Data ([Appendix 1, which is made a part of this Agreement by this reference](#)) signed by the PI and an authorized representative of the Recipient Institution.
5. A list of requested data items with justifications.

CDSRB will review the application materials and additional information may be requested. Approval by the Director of CPDR or designee is required. The PI will be notified in writing. If multiple institutions are involved in a single project, each Recipient Institution will be required to submit their own Confidentiality Agreement for Use and Disclosure of CPDR Data as well as IRB approval.

The Confidentiality Agreement for Use and Disclosure of CPDR Data is a legal document that creates substantial ongoing obligations on the part of the individual signatory in the Recipient Institution with respect to confidentiality, security, use, access, disclosure, and publication of CPDR data, including additional obligations not specified in these policies and procedures. Individuals signing this document, agree to comply, in all respects with the terms and conditions of this agreement.

b. Types of data release

i. Analytic files (case listing for analysis):

Research studies requesting datasets containing CPDR data items require a defined study design and research protocol. Data must be used for the stated purpose only and destroyed upon completion of the study. To keep a study active, researchers must maintain current CPHS and IRB approvals.

ii. Patient Personal Identifiers Data for Patient Contact Studies

Cases for approved 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 CPDR on each patient contacted, noting: date of contact and enrollment status (e.g., non-eligibility, not found, no response, or refusal).

CPDR 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 CPDR.

c. Obtaining CPHS approval

All data disclosure 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 <http://www.oshpd.ca.gov/Boards/CPHS/index.html>
- CPHS Contact:
Phone: (916) 326-3660
E-mail CPHS at cphs-mail@oshpd.ca.gov
- The CPHS requires a letter of support from the CPDR, signed by the Director of CPDR 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 to CDSRB, and staff will provide a signed CPHS Appendix VII (letter of support) for the CPHS review process.

d. Special requirements for research studies involving patient contact

In addition to the requirements set forth above and in the Confidentiality Agreement for Use and Disclosure of CPDR Data, researchers requesting CPDR 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 CPDR was created. A copy of the CPDR brochure, *Frequently Asked Questions* should also be included (<https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/CDSRB/CDPH%20Document%20Library/CPDR/146380-Parkinson-FAQ-ADA.pdf>).
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 CPDR. Any patient who states that he/she does not wish to be contacted again by any researcher must be reported to CPDR in writing.
3. The researcher must notify CPDR if he or she becomes aware of errors or omissions in the CPDR 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 CPDR 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 CPDR data by researchers

Unless written approval for redisclosure from the Director of CPDR or designee has been provided to a data recipient, under no circumstances shall a data recipient redisclose CPDR data. Notwithstanding any other law, the redisclosure of CPDR data is prohibited under HSC 103870.1 (f). If multiple institutions are involved in a single project, each Recipient Institution will be required to submit their own Confidentiality Agreement for Use and Disclosure of CPDR Data as well as IRB approval.

f. Access to CPDR data by research staff

The Recipient Institution may grant access to the CPDR data to the PI and workforce members of his/her research team to carry out a specific assignment on behalf of the Recipient Institution, 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 seeking access must provide information sufficient to justify the request and must maintain confidentiality of the data in accordance with the Confidentiality Agreement for Use and Disclosure of CPDR Data of their Recipient Institution. A copy of the list of individuals who have accessed CPDR data must be provided annually to CDPH/CDSRB per HSC 103870.1 (e).

g. Annual Reporting to CPDR regarding CPDR data disclosure

The Recipient Institution is required to submit the renewal approval letters from the institutional IRB and CPHS. The Recipient Institution is also required to submit a list of individuals who have accessed CPDR 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 CPDR data will be used. If the study is complete, then the Recipient Institution is required to complete the CPDR Data Destruction Acknowledgement Form documenting CPDR data have been destroyed ([Appendix 3, which is made a part of this Agreement by this reference](#)).

III. Publications, Reports, and Statistical Compilations

1. General guidelines

HSC Section 103870.1 requires that reports and statistical compilations do not in any way identify individual cases or individual sources of information.

CDSRB may release publications and make presentations to the public containing aggregate data and conclusions drawn from studying CPDR 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 CPDR incidence and prevalence data. Individual cases or individual sources of information shall not be identified in any way. In situations where data re-identification is possible, the [California Health and Human Services \(CHHS\) Data De-Identification Guidelines](#) must be used to determine the appropriate threshold level of data release (i.e., for geographic areas with small populations).

Recipients of CPDR data may release publications and make presentations to the public containing aggregate data and conclusions drawn from studying CPDR 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 CPDR incidence and prevalence data. Individual cases or individual sources of information shall not be identified in any way. In situations where data re-identification is possible, the [CHHS Data De-Identification Guidelines](#) must be used to determine the appropriate threshold level of data release (i.e., for geographic areas with small populations). Researchers are required to provide an electronic or paper copy of any journal article arising out of their research to the CPDR data custodian and the Director of CPDR.

2. Acknowledgement and Disclaimer

All publications shall contain the following disclaimer:

The collection of Parkinson's disease incidence and prevalence data used in this study was supported by the California Department of Public Health pursuant to HSC Section 103870. 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 CPDR according to HSC Section 103870.1 (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.

Patients should complete the California Department of Public Health Request for Access to Personal Information Form ([Appendix 2, which is made a part of this Agreement by this reference](#)) and provide a copy of identification and address verification. Please follow the instructions on the form to submit your request. Note that for data privacy purposes, CPDR is unable to fulfill requests without a provided Social Security Number. Social Security Number should be provided in the 'Beneficiary ID Number' field on the form.

In the case of a guardian or conservator who is submitting the request on behalf of the patient, an individual should complete the California Department of Public Health Request to Access Personal Information Form by Parent, Guardian or Personal Representative ([Appendix 2](#)) and a legal document establishing the legal authority, a copy of identification, and address verification. For more detailed information, please refer to the instructions on this form.

Appendix 1: Confidentiality Agreement for Use and Disclosure of California Parkinson's Disease Registry Data

The California Parkinson's Disease Registry (hereinafter "CPDR") is a repository of Parkinson's disease patient data collected by the California Department of Public Health (CDPH) under the authority of California Health and Safety Code (HSC) Section 103870. CPDR data files contain medical and other personal information about identified individuals. By law, CPDR data, as defined herein, are confidential, and cannot be disclosed except in accordance with state and federal laws. This Confidentiality Agreement for Use and Disclosure of CPDR data (Agreement) sets forth the information privacy and security requirements that the Parties, as defined herein, are obligated to follow with respect to all CPDR data. By entering into this Agreement, Parties agree to protect the privacy and provide for the security of all CPDR data in compliance with all state and federal laws applicable to the CPDR data.

The _____ (hereinafter "Recipient Institution")
(Name of institutional recipient)

has applied to CDSRB/California Parkinson's Disease Registry (hereinafter "CPDR Data Custodian")
(Name of CPDR Data Custodian)

for a copy of certain specified CPDR data to be disclosed to

_____ (hereinafter "Principal Investigator")
(Name of Primary individual recipient)

(collectively with "Recipient Institution" and "CPDR Data Custodian," the "Parties")

for the following proposed use: _____
(Brief description or reference to application)

In consideration for the CPDR Data Custodian's disclosure of CPDR data to Principal Investigator, Recipient Institution and Principal Investigator represent, warrant, and agree as follows:

I. Supersession: This Agreement supersedes any prior CPDR Agreement, or other agreement concerning CPDR data, between CPDR Data Custodian and Recipient Institution.

II. Definitions: For the purposes of this Agreement:

"Access to data" is defined as the granting of the right to examine data.

"Aggregate data" is defined as statistical information derived from CPDR data that relates to a group or category of services or individuals. Aggregate data does not include any individual item of data that represents a person, whether identified,

identifiable or anonymous, and from which no information about an identifiable or anonymous person can be obtained in any manner. The aggregate data is typically shown in table form as counts, percentages, rates, averages, or other statistical groupings.

“Breach” is defined as:

1. the acquisition, access, use, or disclosure of CPDR data in violation of any state or federal law or in a manner not permitted under this Agreement which compromises the security, confidentiality or integrity of the information; or
2. the same as the definition of "breach of the security of the system" set forth in California Civil Code section 1798.29(f).

"CPDR data" is defined as all information relating to cases of Parkinson's disease collected at any time by the CDPH or any other individual or institution under the authority of HSC Section 103870 and predecessor statutes. CPDR data also includes all documents, files or other records, regardless of format or medium, containing CPDR data (whether alone or in combination with other data).

"Disclosure of data" is defined as the release, transfer, provision of, access to, or divulging in any manner of information outside the entity holding the information. Disclosure of data includes all mediums of CPDR data, including written, oral, and electronic.

"Principal Investigator" is defined as the individual that the Recipient Institution designated in its request to receive CPDR data from the CPDR and who is principally responsible for undertaking the proposed use.

"Recipient Institution" is defined as the unit of government, institution, agency, the corporation, or other entity that has requested CPDR data, any other unit of government, institution, agency, corporation or other entity that owns or controls the recipient institution or of which the recipient institution is a constituent part, and includes the Principal Investigator and other workforce members of the Recipient Institution.

"Reports and statistical information" is defined as reports, articles, special analyses, studies, and other publications and communications that contain aggregate CPDR data.

"Research" shall have the same meaning as the definition as 45 C.F.R. section 46.102, subdivision (d).

“Security Incident” is defined as:

1. an attempted breach;
2. the attempted or successful modification or destruction of CPDR data, in

violation of any state or federal law or in a manner not permitted under this Agreement; or

3. the attempted or successful modification or destruction of, or interference with, Recipient Institution's system operations in an information technology system, that negatively impacts the confidentiality, availability or integrity of CPDR data; or
4. any event that is reasonably believed to have compromised the confidentiality, integrity, or availability of an information asset, system, process, data storage, or transmission. Furthermore, an information security incident may also include an event that constitutes a violation or imminent threat of violation of information security policies or procedures, including acceptable use policies.

"Sources of information" is defined as hospitals and other facilities or agencies providing diagnostic or treatment services to patients with Parkinson's disease, and physicians and other health care practitioners diagnosing or providing treatment to Parkinson's patients that have provided information contained in CPDR data.

"Use" is defined as the sharing, employment, application, utilization, examination, or analysis of information.

"Workforce Member" is defined as an employee, volunteer, trainee, or other person whose conduct, in the performance of work for Recipient Institution is under the direct control of Recipient Institution, whether or not they are paid by the Recipient Institution and includes the Principal Investigator.

III. California Health and Safety Code Section 103870 Authority:

A. California Health and Safety Code (HSC) Section 103870 is the primary authority which governs the confidentiality of CPDR Data and contains various provisions relating to use, access, disclosure, and publication of CPDR data. These provisions may be different from the laws, regulations or policies applicable to other data used by Recipient Institution and Principal Investigator. Recipient Institution certifies that:

1. they have reviewed HSC Section 103870, the California Department of Public Health, Chronic Disease Surveillance and Research Branch, "Data Disclosure Policies and Procedures from the California Parkinson's Disease Registry" (hereinafter "CPDR Data Disclosure Policies and Procedures"), and the terms and conditions of this Agreement;
2. they have had a full opportunity to discuss any questions or concerns they may have regarding the interpretation of HSC Section 103870 and their duties and obligations under the statute

and the terms and conditions of this Agreement with CPDR;

3. any such questions or concerns have been resolved to their satisfaction; and
4. on the basis of the foregoing review and discussions, they agree to receive and use CPDR data in conformity with HSC Section 103870, the terms and conditions of the CPDR Data Disclosure Policies and Procedures, and the terms and conditions of this Agreement.

B. Recipient Institution agrees to comply with the requirements of HSC Section 103870, any and all other applicable Federal and State laws or regulations relating to confidentiality, security, use, access, and disclosure of CPDR data, and the CPDR Data Disclosure Policies and Procedures.

IV. Health Insurance Portability and Accountability Act of 1996 (HIPAA) Authority:

A. CDPH and CPDR HIPAA Status: CDPH is a “hybrid entity” for purposes of applicability of the federal regulations entitled "Standards for Privacy of Individually Identifiable Health Information" ("Privacy Rule") (45 C.F.R. Parts 160, 162, and 164) promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 U.S.C. §§ 1320d - 1320d-8) (as amended by Subtitle D Privacy, of the Health Information Technology for Economic and Clinical Health (HITECH) Act (Pub. L. 111–5, 123 Stat. 265–66)). The California Parkinson’s Disease Registry has not been designated by the CDPH as, and is not, one of the HIPAA-covered “health care components” of CDPH. (45 C.F.R. § 164.103.) The legal basis for this determination is as follows:

1. The California Parkinson’s Disease Registry is not a component of CDPH that would meet the definition of a covered entity or business associate if it were a separate legal entity. (45 C.F.R. §§ 164.105(a)(2)(iii)(D); 160.103 (definition of “covered entity”)); and
2. The HIPAA Privacy Rule creates a special rule for a subset of public health activities whereby HIPAA cannot preempt state law if, “[t]he provision of state law, including state procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.” (45 C.F.R. § 160.203(c) [HITECH Act, § 13421, sub. (a)].) [NOTE: See State laws and regulations listed in Attachment A.]

B. CDPH is a “Public Health Authority”: CDPH is a “public health authority” as that term is defined in the Privacy Rule. (45 C.F.R. §§ 164.501; 164.512(b)(1)(i).)

C. CPDR Data Use and Disclosure Permitted by HIPAA: To the extent a disclosure or use of CPDR data may also be considered a disclosure or use of “Protected Health Information” (PHI) of an individual, as that term is defined in part 160.103 of Title 45, Code of Federal Regulations, the following Privacy Rule provisions apply to permit such CPDR data disclosure and/or use by CDPH and Research Institution, without the consent or authorization of the individual who is the subject of the PHI:

1. HIPAA cannot preempt state law if, “[t]he provision of state law, including state procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention;” (45 C.F.R. § 160.203(c) [HITECH Act, § 13421, sub. (a)].) [NOTE: See state laws and regulations listed in Attachment A];
2. A covered entity may disclose PHI to a “public health authority” carrying out public health activities authorized by law; (45 C.F.R. § 164.512(b));
3. A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law. (45 C.F.R. §§ 164.502 (a)(1), 164.512(a)(1).); and
4. Other, non-public health-specific provisions of HIPAA may also provide the legal basis for all or specific CPDR data uses and disclosures.

D. No HIPAA Business Associate Agreement or Relationship between CDPH/CPDR Data Custodian and Recipient Institution: This Agreement and the relationship it memorializes between CDPH/CPDR Data Custodian and Recipient Institution do not constitute a business associate agreement or business associate relationship pursuant to 45 C.F.R. § 160.103 (definition of “business associate”). The basis for this determination is 45 C.F.R. §160.203(c) (see, also, [HITECH Act, § 13421, subdivision. (a)].) [NOTE: See state laws and regulations listed in Attachment A.] Accordingly, this Agreement is not intended to nor at any time shall result in or be interpreted or construed as to create a business associate relationship between CDPH/CPDR Data Custodian and Recipient Institution. By the execution of this Agreement, CDPH and Recipient Institution expressly disclaim the existence of any business associate relationship.

V. Minimum Necessary: Only the minimum necessary amount of CPDR data required to perform necessary business functions may be copied, downloaded, or exported.

Recipient Institution certifies that the CPDR data they have requested is the minimum necessary for the above-referenced proposed use. If Recipient Institution receives CPDR data that are not necessary for the above-referenced proposed use, they will immediately notify the CPDR Data Custodian and destroy the unneeded CPDR data.

- VI. Use Restrictions: Recipient Institution, the Principal Investigator, and members of his/her research team with access to CPDR data, shall safeguard the CPDR data to which they have access to from unauthorized use. Recipient Institution agrees to use the requested CPDR Data in strict conformity with the proposed use set forth above. Recipient Institution agrees not to use the CPDR data for any other purpose than as proposed in this Agreement, so long as the purpose is to determine the sources of Parkinson's disease and/or evaluate measures designed to eliminate, alleviate, or ameliorate their effect.
- VII. Access to CPDR Data: The Recipient Institution may grant access to the CPDR data to the Principal Investigator and workforce members of his/her research team to carry out a specific assignment on behalf of the Recipient Institution, 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 seeking access must provide information sufficient to justify the request and individual must agree to maintain the confidentiality of the data in accordance with the Confidentiality Agreement for Use and Disclosure of CPDR Data of their Recipient Institution. Recipient Institution must maintain a list 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 CPDR data will be used. A copy of the list must be provided annually to the CPDR Data Custodian. Except as provided in this paragraph, Recipient Institution agrees not to grant access to the CPDR data to any person or entity, nor shall it permit persons to whom it has granted access to authorize other persons or entities to have access to the CPDR data.
- VIII. Disclosure Restrictions: Recipient Institution, and its workforce members, shall safeguard CPDR data to which they have access to from unauthorized disclosure. Unless written approval for redisclosure from the Director of CPDR or designee has been provided to a data recipient, under no circumstances shall a data recipient redisclose CPDR data. Notwithstanding any other law, the redisclosure of CPDR data is prohibited under HSC 103870.1 (f). If multiple institutions are involved in a single project, each Recipient Institution will be required to submit their own Confidentiality Agreement for Use and Disclosure of CPDR Data as well as IRB approval.
- IX. Accuracy in CPDR Data: Recipient Institution agrees to notify the CPDR Data Custodian and the Director of CPDR if he or she becomes aware of errors or omissions in the CPDR data, or of patient vital statistics or address information that is more current than the CPDR data provided to them under this Agreement.
- X. Publications: Recipient Institution and Principal Investigator may include aggregate data, conclusions drawn from studying CPDR data, and case counts derived from CPDR

data such as incidence and mortality counts (provided that such case counts do not in any way identify individual cases or sources of information) in professional journals, public reports, presentations, press releases and other publications. In situations where data re-identification is possible, the [California Health and Human Services Data De-Identification Guidelines](#) must be used to determine the appropriate threshold level of data release (i.e., for geographic areas with small populations). A copy shall be provided to the CPDR Data Custodian and all publications shall contain the acknowledgement and disclaimer set forth in the CPDR Data Disclosure Policies and Procedures, and a copy shall be provided to the CPDR Data Custodian and the Director of CPDR.

- XI. Institution Review Board Approval for Research: If the proposed use is for research, Recipient Institution certifies that it has obtained approval for the proposed use from the Recipient Institution's 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, and that they will carry out the proposed use in accordance with such approval, except that the terms and conditions of this confidentiality agreement shall take precedence when in conflict. Principal Investigator agrees to provide documentation of initial IRB approval and any renewals. If the proposed research involves patient contact based on information received from CPDR, the Recipient Institution agrees to follow the special requirements required by CPDR for patient contact studies in Section V.6.c. of the CPDR Data Disclosure Policies and Procedures, including obtaining approval for the proposed use from the California Committee for Protection of Human Subjects.
- XII. Safeguards: Recipient Institution shall implement administrative, physical, and technical safeguards that reasonably and appropriately protect the privacy, confidentiality, security, integrity, and availability of CPDR Data. Recipient Institution shall develop and maintain a written information privacy and security program that includes administrative, technical and physical safeguards appropriate to the size and complexity of the Recipient Institution's operations and the nature and scope of its activities in performing its legal obligations and duties (including performance of its duties and obligations under this Agreement), and which incorporates the requirements of Section XIII, Security, below. Recipient Institution shall provide CPDR Data Custodian with Recipient Institution's current and updated policies.
- XIII. Security: Recipient Institution shall take all steps necessary to ensure the continuous security of all computerized data systems containing CPDR data. These steps shall include, at a minimum:
- A. Providing a level and scope of security that is at least comparable to the level and scope of security established by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix III- Security of Federal Automated Information Systems, and/or NIST 800-53 (version 4 or subsequent approved versions) which sets forth guidelines for automated information systems in Federal agencies; and

- B. In case of a conflict between any of the security standards contained in any of the aforementioned sources of security standards, the most stringent shall apply. The most stringent means that safeguard which provides the highest level of protection to CPDR data from breaches and security incidents.

XIV. Security Officer: Recipient Institution shall designate a Security Officer to oversee its compliance with this Agreement and for communicating with CDPH and CPDR Data Custodian on matters concerning this Agreement. Such designation is set forth in Attachment B, which is made a part of this Agreement by this reference.

XV. Training: Recipient Institution shall provide training on its obligations under this Agreement, at its own expense, to all of its workforce members who assist in the performance of Recipient Institution's obligations under this Agreement, or otherwise use or disclose CPDR data.

- A. Recipient Institution shall require each workforce member who receives training to receive and sign a certification, indicating the workforce member's name and the date on which the training was completed.

- B. Recipient Institution shall retain each workforce member's written certifications for CDPH or CPDR Data Custodian inspection for a period of three (3) years following the termination of this Agreement.

XVI. Workforce Member Discipline: Recipient Institution shall impose discipline that it deems appropriate (in its sole discretion) on such employees and other Recipient Institution workforce members under Recipient Institution's direct control who intentionally or negligently violate any provisions of this Agreement.

XVII. Recipient Institution Breach and Security Incident Responsibilities:

- A. Notification to CDPH of Breach or Security Incident: Recipient Institution shall notify CDPH **immediately by telephone call plus email or fax** upon the discovery of a breach (as defined in this Agreement), **or within twenty-four (24) hours by email or fax** of the discovery of any security incident (as defined in this Agreement). Notification shall be provided to the CDPH Program Manager, the CDPH Privacy Officer and the CDPH Chief Information Security Officer, using the contact information listed in Section XVII(G), below. If the breach or security incident occurs after business hours or on a weekend or holiday and involves CPDR Data in electronic or computerized form, notification to CDPH shall be provided by calling the CDPH IT Service Desk at the telephone numbers listed in Section XVII(G), below. For purposes of this Section, breaches and security incidents shall be treated as discovered by Recipient Institution as of the first day on which such breach or security incident is known to Recipient Institution, or, by exercising reasonable diligence would have been known to Recipient Institution. Recipient Institution shall be deemed to have knowledge of a breach or security incident if such breach or

security incident is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the breach or security incident, who is a workforce member or agent of the Recipient Institution.

Recipient Institution shall take:

1. prompt corrective action to mitigate any risks or damages involved with the breach or security incident and to protect the CPDR data operating environment; and,
2. any action pertaining to a breach required by applicable federal or state laws, including, specifically, California Civil Code section 1798.29.

B. Investigation of Breach: Recipient Institution shall immediately investigate such breach or security incident, and within seventy-two (72) hours of the discovery, shall inform the CDPH Program Manager, the CDPH Privacy Officer, and the CDPH Chief Information Security Officer of:

1. what data elements were involved and the extent of the data involved in the breach, including, specifically, the number of individuals whose personal information was breached; and
2. a description of the unauthorized persons known or reasonably believed to have improperly used the CPDR data and/or a description of the unauthorized persons known or reasonably believed to have improperly accessed or acquired the CPDR data, or to whom it is known (or reasonably believed) to have had the CPDR data improperly disclosed to them; and
3. a description of where the CPDR data is known or believed to have been improperly used or disclosed; and
4. a description of the known or probable causes of the breach or security incident; and
5. whether Civil Code section 1798.29 or any other federal or state laws requiring individual notifications of breaches have been triggered.

C. Written Report: Recipient Institution shall provide a written report of the investigation to the CDPH Program Manager, the CDPH Privacy Officer, and the CDPH Chief Information Security Officer within five (5) working days of the discovery of the breach or security incident. The report shall include, but not be limited to, the information specified above, as well as a full, detailed corrective action plan, including information on measures

that were taken to halt and/or contain the breach or security incident, and measures to be taken to prevent the recurrence of such breach or security incident.

- D. Notification to Individuals: If notification to individuals whose information was breached is required under state or federal law, and regardless of whether Recipient Institution is considered only a custodian and/or non-owner of the CPDR data, Recipient Institution shall, at its sole expense, and at the sole election of CDPH, either:
1. make notification to the individuals affected by the breach (including substitute notification), pursuant to the content and timeliness provisions of such applicable state or federal breach notice laws. The CDPH Privacy Officer shall approve, in writing, the time, manner and content of any such notifications, prior to the transmission of such notifications to the individual(s); or
 2. cooperate with and assist CDPH in its notification (including substitute notification) to the individuals affected by the breach.
- E. Submission of Sample Notification to California Attorney General: If notification to more than 500 individuals is required pursuant to California Civil Code section 1798.29, Recipient Institution shall, at its sole expense, and at the sole election of CDPH, either:
1. electronically submit a single sample copy of the security breach notification, excluding any personally identifiable information, to the California Attorney General pursuant to the format, content and timeliness provisions of Section 1798.29, subdivision (e). Recipient Institution shall inform the CDPH Privacy Officer of the time, manner and content of any such submissions, prior to the transmission of such submissions to the Attorney General; or
 2. cooperate with and assist CDPH in its submission of a sample copy of the notification to the California Attorney General.
- F. Public Statements: Recipient Institution shall cooperate with CDPH in developing content for any public statements regarding Breaches or Security Incidents related to Recipient Institution and shall not provide any public statements without the express written permission of CDPH. Requests for public statement(s) by any non-party about a breach or security incidents shall be directed to the CDPH Program Manager, the CDPH Privacy Officer and the CDPH Chief Information Security Officer, using the contact information listed in Section XVII(G), below.
- G. CDPH Contact Information: To direct communications to the above referenced CDPH staff, Recipient Institution shall initiate contact as

indicated below. CDPH reserves the right to make changes to the contact information by giving written notice to Recipient Institution. Said changes shall not require an amendment to this Agreement.

CDPH Program Manager	CDPH Privacy Officer (and CDPH Office of Legal Services (OLS))	CDPH Chief Information Security Officer (and CDPH IT Service Desk)
<p>Mark Damesyn, Dr.PH. Chronic Disease Surveillance and Research Branch California Department of Public Health 1631 Alhambra Blvd, Suite 200 Sacramento, CA 95816</p> <p>Email: Mark.Damesyn@cdph.ca.gov Telephone: (916) 731-2500</p>	<p>Privacy Officer Privacy Office, c/o Office of Legal Services California Department of Public Health 1415 L Street, Suite 500 Sacramento, CA 95814</p> <p>Email: privacy@cdph.ca.gov Telephone: (877) 421-9634</p> <p>OLS: Telephone: (916) 558-1710</p>	<p>Chief Information Security Officer Information Security Office California Department of Public Health P.O. Box 997413, MS 6300 Sacramento, CA 95899-7413</p> <p>Email: cdph.infosecurityoffice@cdph.ca.gov Telephone: IT Service Desk (916) 440-7000 or (800) 579-0874</p>

XVIII. Limited License: This Agreement creates a revocable, non-transferable limited license for Recipient Institution to use selected CPDR data provided to them. Neither Recipient Institution nor Principal Investigator shall acquire any ownership, title or other interest in any CPDR data or any copy of CPDR data provided to them.

XIX. Subpoena, Search Warrant, or Other Litigation Involved Requests: In the event that a subpoena, search warrant, or other litigation-involved request for CPDR data provided by the CPDR Data Custodian is received by Recipient Institution or Principal Investigator, Recipient Institution shall immediately notify the Director of CPDR and the CDPH Office of Legal Services by telephone call using the contact information listed in Section XVII(G), above, in order to allow CDPH to follow the procedures and restrictions imposed by California Health and Safety Code section 103870.1, subdivision (f). CDPH shall be the party with sole authority to determine whether any, and specifically what, information may be produced.

XX. Indemnification: Recipient Institution agrees to indemnify, defend and hold harmless the State of California and the CPDR Data Custodian and their respective agencies, officers, directors, employees and agents from and against any and all claims, losses, damages, costs, liabilities or other expenses, including attorneys' fees, that result from or arise directly or indirectly out of or in connection with any negligent act or omission or willful misconduct of Recipient Institution the CPDR data, including, without limitation, any violations of Recipient Institution's responsibilities under this Agreement.

XXI. Term of Agreement: Unless otherwise terminated earlier in accordance with the provisions set forth herein, this Agreement shall remain in effect for three (3) years after the signature date of the Director of CPDR or designee below. After three (3) years, this Agreement will expire without further action. If the Recipient Institution wishes to extend this Agreement, they may do so by reviewing, updating, and reapplying under this Agreement. The CPDR Data Custodian reserves the right to terminate Recipient Institution's this Agreement by written notice at any time without cause. Upon receipt of such notice, Recipient Institution shall immediately and permanently destroy all copies of CPDR Data in its custody in a manner as prescribed in Section XXI, below.

XXII. Destruction of CPDR Data: Upon expiration or termination of this Agreement for any reason, Recipient Institution agrees to securely destroy all files, documents or other records containing CPDR data in their custody. If destruction is not feasible, Recipient Institution shall provide a written explanation to the CPDR Data Custodian and the Director of CPDR if there is a health or research justification for retention or retention required by law. Recipient Institution's and Principal Investigator's obligations under this Exhibit shall continue until they destroy the CPDR data; provided however, that on expiration or termination of this Agreement, Recipient Institution and Principal Investigator shall not further use or disclose the CPDR data except as required by state or federal law. Destruction means physical destruction of files, documents or other records. Immediately following the destruction of CPDR data, Recipient Institution agrees to provide the CPDR Data Custodian with a written declaration, executed by an authorized representative of Recipient Institution, stating that the CPDR data have been securely destroyed ([Appendix 3](#)).

XXIII. Amendment: The parties acknowledge that Federal and State laws relating to information security and privacy are rapidly evolving and that amendment of this Agreement may be required to provide for procedures to ensure compliance with such laws. The parties specifically agree to take such action as is necessary to implement new standards and requirements imposed by regulations and other applicable laws relating to the security or privacy of CPDR Data. Upon the CPDR Data Custodian's request, Recipient Institution agrees to promptly enter into negotiations with the CPDR Data Custodian concerning an amendment to this Agreement embodying written assurances consistent with new standards and requirements imposed by regulations and other applicable laws. The CPDR Data Custodian may terminate this Agreement upon thirty (30) days written notice in the event:

1. Recipient Institution does not promptly enter into negotiations to amend this Agreement when requested by the CPDR Data Custodian pursuant to this Section, or
2. Recipient Institution does not enter into an amendment providing assurances regarding the safeguarding of CPDR data that the CPDR Data Custodian in its sole discretion deems sufficient to satisfy the standards and requirements of applicable laws and regulations relating to the security or privacy of CPDR data.

- XXIV. Assistance in Litigation or Administrative Proceedings: Recipient Institution shall make itself and any subcontractors, workforce employees or agents assisting Recipient Institution in the performance of its obligations under this Agreement between Recipient Institution and the CPDR Data Custodian, available to CDPH at no cost to CPDR Data Custodian to testify as witnesses, in the event of litigation or administrative proceedings being commenced against CPDR Data Custodian, its director, officers or employees based upon claimed violation of laws relating to security and privacy, which involves inactions or actions by the Recipient Institution, except where Recipient Institution or its subcontractor, workforce employee or agent is a named adverse party.
- XXV. Disclaimer: CPDR Data Custodian makes no warranty or representation that compliance by Participant with this Agreement will be adequate or satisfactory for Recipient Institution's own purposes or that any information in Recipient Institution's possession or control, or transmitted or received by Recipient Institution, is or will be secure from unauthorized use or disclosure. Recipient Institution is solely responsible for all decisions made by Recipient Institution regarding the safeguarding of CPDR data.
- XXVI. Transfer of Rights: Neither Recipient Institution nor Principal Investigator have a right to and shall not delegate, assign, or otherwise transfer or delegate any of its rights or obligations under this Agreement to any other person or entity. Any such transfer of rights shall be null and void.
- XXVII. No Third-Party Beneficiaries: Nothing express or implied in the terms and conditions of this Agreement is intended to confer, nor shall anything herein confer, upon any person other than Recipient Institution, any rights, remedies, obligations or liabilities whatsoever.
- XXVIII. Interpretation: The terms and conditions in this Agreement shall be interpreted as broadly as necessary to implement and comply with regulations and applicable State and Federal laws. The parties agree that any ambiguity in the terms and conditions of this Agreement shall be resolved in favor of a meaning that complies and is consistent with Federal and State laws.
- XXIX. Survival: The respective rights and obligations of Recipient Institution and Principal Investigator under Sections XII, XIII, and XVII of this Agreement shall survive the termination or expiration of this Agreement.
- XXX. Irreparable Harm: Recipient Institution acknowledges that if it fails to comply with any of their obligations under this confidentiality agreement, the CPDR Data Custodian and CDPH may suffer immediate, irreparable harm for which monetary damages may not be adequate. Recipient Institution agrees that, in addition to any other remedies provided at law or in equity, the CPDR Data Custodian and/or CDPH shall be entitled to seek injunctive relief to enforce the provisions of this agreement.
- XXXI. Entire Agreement: This Agreement, including all attachments, constitutes the entire agreement between the parties. Any and all modifications of this Agreement must be

in writing and signed by all parties. Any oral representations or agreements between the parties shall be of no force of effect.

XXXII. Severability: The invalidity in whole or in part of any provisions of this Agreement shall not void or affect the validity of any other provisions of this Agreement.

XXXIII. Choice of Law and Venue: The laws of the state of California will govern any dispute from or relating to this Agreement. The parties submit to the exclusive jurisdiction of the state of California and federal courts for or in Sacramento, California and agree that any legal action or proceeding relating to the Agreement may only be brought in those courts.

XXXIV. Notwithstanding any other provision of this agreement, the CPDR Data Custodian shall have no obligation to provide CPDR data to Recipient Institution unless and until this agreement is approved by the Director of CPDR or designee.

For Recipient Institution:

I have read the foregoing agreement. I have the authority to execute this confidentiality agreement on behalf of the Recipient Institution. By signing below, I make the agreements, and certifications contained therein on behalf of the Recipient Institution. I understand that these are material representations of fact upon which reliance was placed when this transaction was entered into.

Signature

Dated

Printed Name and Title

Principal Investigator:

I have read and understood the foregoing agreement.

Signature

Dated

Printed Name and Title

APPROVAL BY CALIFORNIA DEPARTMENT OF PUBLIC HEALTH, CHRONIC DISEASE SURVEILLANCE AND RESEARCH BRANCH:

Signature

Dated

Printed Name and Title

Attachment A

State Law Authority for:

(1) Use and Disclosure of CPDR Data

A. Legal Authority:

1. Health and Safety Code Section 103870.1, subdivisions (a-b):

“(a) 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, and who agree, in writing, to maintain confidentiality, may be authorized access to confidential information collected by the department pursuant to Section 103870. (b) The department may enter into agreements to furnish confidential information to other states’ Parkinson’s disease registries, federal Parkinson’s disease control agencies, local health officers, or health researchers for the study of Parkinson’s 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.”

2. California Information Practices Act:

California Civil Code section 1798.24, subdivision (t), provides in part as follows: “An agency shall not disclose any personal information in a manner that would link the information disclosed to the individual to whom it pertains unless the information is disclosed, as follows: to the University of California, [or] a nonprofit educational institution [...] conducting scientific research, if the request for information is approved by the Committee for the Protection of Human Subjects (CPHS)....”

Attachment B
Recipient Institution Breach and Security Incident Contact Information.

The following Recipient Institution contact information must be included in the executed Agreement

Recipient Institution Principal Investigator

Name: _____

Title: _____

Address: _____

City: _____

State, Zip Code: _____

Telephone, Fax: _____

E-mail: _____

Recipient Institution Privacy Officer

Name: _____

Title: _____

Address: _____

City: _____

State, Zip Code: _____

Telephone, Fax: _____

E-mail: _____

Recipient Institution Chief Information Security Officer (and IT Service Desk)

Name: _____

Title: _____

Address: _____

City: _____

State, Zip Code: _____

Telephone, Fax: _____

E-mail: _____

Appendix 2: CDPH Patient Record Request Form

Please visit the following links to obtain the CDPH Patient Record Request Form(s). Note that for data privacy reasons, CPDR cannot fulfill requests without a provided Social Security Number (SSN). SSN should be entered in the 'Beneficiary ID Number' field on the form(s) below.

Request for Access to Personal Information:

<https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/cdph6236.pdf>

Request to Access Personal Information by Parent, Guardian or Personal Representative:

<https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/cdph6237.pdf>

Appendix 3: Data Destruction Acknowledgment



California Department of Public Health

Data Destruction Acknowledgment

PI Name: _____ PI Institution: _____

Project: _____

Project Approval Date: _____

This is to certify that ALL California Parkinson's Disease Registry (CPDR) 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