New Jersey Integrated Population Health Data (iPHD) Project

DATA USE AND ACCESS POLICY

Approved January 21, 2022

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1.0 INTRODUCTION

1.1 PURPOSE

This policy establishes the rules governing access, use, and disclosure of de-identified data collected, stored, and maintained in the Integrated Population Health Data (iPHD) Project operated by the Center for State Health Policy (CSHP), a unit of the Institute for Health and Health Care Policy and Aging Research within Rutgers Biomedical and Health Sciences at Rutgers, the State University of New Jersey ("Rutgers"). iPHD Authorized Data Users are obligated to comply with this policy and all subsequent amendments adopted by the iPHD Governing Board.

1.2 AUTHORITY

This Data Use & Access Policy is authorized under P.L. 2015, c. 193, an Act concerning the establishment of a process to integrate certain health data and other data from publicly supported programs for population health research and supplementing Title 30 of the Revised Statutes ("iPHD Project Law").

1.3 BACKGROUND

By enacting the iPHD Project Law, the New Jersey Legislature and Governor established a process to integrate health and other data from publicly supported programs for population health research for the purpose of: (1) improving the public health, safety, security and well-being of New Jersey residents; and (2) improving the overall cost-efficiency of government assistance programs. The iPHD Project Law establishes a Governing Board and oversight process and authorizes iPHD Project operations within the Rutgers Center for State Health Policy (CSHP). The legislation requires that CSHP will comply with all applicable federal and state laws and regulations governing the privacy and security of personal health information and other data, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 (HIPAA; Pub.L. 104–191, 110 Stat. 1936), 42 C.F.R. Part 2, and other laws and regulations applicable to data received or distributed by CSHP.

The iPHD Project Law recognized that New Jersey administrative departments and agencies create and maintain Personally Identifiable Information (PII) and Aggregated Data sets in performance of their functions. A process by which agencies or authorized Researchers can access data will help improve the value of those data

sets. The linkage of multiple data sources and application of valid research methods can help identify population trends and individual and community determinants of the health, safety, security, and well-being of New Jersey residents.

The establishment of a secure, statewide iPHD Project containing certain data from New Jersey departments and agencies relating to health and publicly supported programs will facilitate project-by-project approved analysis and research on the most effective strategies of improving the health, safety, security, and well-being of New Jersey residents and the overall cost-efficiency of government assistance programs. Pursuant to the iPHD Project Law, Rutgers CSHP has responsibility for the operation of the iPHD Project under the direction of the iPHD Governing Board.

1.4 DEFINITIONS

"Access" means the ability for an Authorized Data User to view, download, and/or extract data in the systems maintained by the iPHD.

"Aggregated Data" means group summary data that do not include Personally Identifiable Information.

"Anonymous Data" means data that do not include Personally Identifiable Information.

"Applicant" is a Researcher that has the meaning set forth in N.J.S.A. 30:4D-66, as it has or will be amended, and as described below.

"Authorized Data User" refers to an entity eligible to receive data from the iPHD Project, as specified in an executed Data Use Agreement (DUA), unless prohibited by state or federal law.

"Breach" means the acquisition, Access, Use, or Disclosure of Unsecured Protected Health Information or Personally Identifiable Information not authorized by HIPAA, Part 2, or other federal or state law, or the terms of a Data Use Agreement or Business Associate Agreement, as applicable, which compromises the Security or Integrity of the Protected Health Information or Personally Identifiable Information.

"Business Associate Agreement" ("BAA") means the agreement between a Covered Entity and a Business Associate, or between a Business Associate and a Subcontractor, as such terms are defined under HIPAA at 45 C.F.R. § 160.103, as it has or will be amended.

"Cleaned Data" means data that have been refined so that they meet database standards for the meaning of the variable field, what values the field may contain, and how the entries should be formatted or structured.

"Confidentiality" means that data or information is not made available or disclosed to unauthorized persons or processes pursuant to applicable federal and state privacy laws.

"Data Use Agreement" ("DUA") means the document approved Researchers will be required to sign prior to accessing or receiving iPHD data.

"De-identified Data" means data that do not identify an individual and with respect to which there is no reasonable basis to believe that the data can be used to identify an individual. Data are considered to be De-identified Data if they meet the standards for de-identification set forth under HIPAA at 45 C.F.R. § 164.514(b), as it has or will be amended.

"Disclosure" means the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information as defined under HIPAA at 45 C.F.R. § 160.103, as it has or will be amended. The meaning of "Disclosure" shall also apply to those capitalized terms used herein that are in the plural or in any tense or variant of the term "Disclosure", such as "Disclose", "Discloses", "Disclosing" and "Disclosed".

"Governing Board" or "Board" means the entity charged with responsibility for governing the iPHD Project established pursuant to section N.J.S.A. 30:4D-66, as it has or will be amended.

"HIPAA" means the "Health Insurance Portability and Accountability Act of 1996," Pub. L. 104-191, as it has or will be amended, and any regulations promulgated thereunder by the Secretary of the U.S. Department of Health and Human Services ("HHS").

"Integrated Data" refers to data linked from multiple sources within the iPHD Project.

"Institutional Review Board" (IRB) means an entity established pursuant to federal regulations set forth at 45 C.F.R. § 46 with a Federal-wide Assurance for the Protection of Human Subjects approved by the U.S. Department of Health and Human Services, Office for Human Research Protections.

"iPHD Data" refers to data approved by the Board maintained for the retention period approved by the Board.

"iPHD Project" or "Project" means the Integrated Population Health Data Project established pursuant to N.J.S.A. 30:4D-66, as it has or will be amended.

"Limited Data Set" means Protected Health Information that excludes the identifiers listed under HIPAA at 45 C.F.R. § 164.514(e)(2), as it has or will be amended.

"Open Public Records Request" refers to a formal request to provide information to a third party in compliance with the New Jersey Open Public Records Act, P.L. 2001, c. 404, as it has or will be amended.

"Partner Agency" means any governmental entity with which the iPHD Project has a current, executed Data Use Agreement, or that otherwise contributes data to the iPHD Project.

"Personally Identifiable Information" means—any information about an individual maintained by an agency, including (1) any information that can be used to distinguish or trace an individual's identity, such as name, social security number, date and place of birth, mother's maiden name, or biometric records; and (2) any other information that is linked or linkable to an individual, such as medical, educational, financial, and employment information. (NIST Special Publication 800-122 Guide to Protecting Confidentiality of Personally Identifiable Information).

"Protected Health Information" has the meaning set forth in HIPAA at 45 C.F.R. § 160.103, as it has or will be amended.

"Publicly Supported Programs Data" has the meaning set forth in N.J.S.A. 30:4D-66, as it has or will be amended.

"Research" means a systematic investigation, including research development, testing, and evaluation, that is designed to develop or contribute to generalizable knowledge as defined in 45 C.F.R. § 46.102(l), as it has or will be amended.

"Researcher" means a private or public entity that conducts research under the review and monitoring of an IRB and has received approval from the Partner Agency for the purpose of requested data elements.

"Research Advisory Committee" or "Committee" refers to the committee constituted by the iPHD Governing Board to advise the Board on the quality and rigor of research proposals submitted for the Board's consideration, the research qualifications of applicant personnel, and the degree to which the proposal is consistent with the approved iPHD Research Priorities.

"Research Consortium" means a group of Researchers from New Jersey academic institutions and from medical schools affiliated with New Jersey universities constituted to facilitate actionable population health research to help improve health outcomes for New Jersey residents, as well as promote social science research in New Jerseys' research institutions.

"Research Priorities" means the list of policy and programmatic questions related to the improvement of population health requiring research that has been developed through the engagement of a diverse group of Researchers and academic institutions throughout New Jersey and approved by the iPHD Governing Board. The Research Priorities shall reflect actionable or addressable current or future needs related to health outcomes (including social determinants of health) in New Jersey that require innovative solutions.

"Security" includes measures to ensure the confidentiality, integrity, and availability of iPHD Data, to protect against reasonably anticipated threats or hazards to the security and integrity of the iPHD Data, and to protect against any reasonably anticipated uses or Disclosures of the iPHD Data that are not permitted by this Data Use and Access Policy.

"Security Incident" has the meaning set forth in HIPAA at 45 C.F.R. § 164.304, as it has or will be amended, but does not include attempted but unsuccessful Security Incidents that are inconsequential or harmless in nature, such as pings and port scans.

"Statistically Identifiable Data" means data that, because they represent small groups of individuals or unique characteristics of a population, can reasonably be expected to be re-identified.

"Unsecured Protected Health Information" has the meaning set forth in HIPAA at 45 C.F.R. § 164.402, as it has or will be amended.

"Use" has the meaning set forth in HIPAA at 45 C.F.R. § 160.103, as it has or will be amended. The meanings given to the term "Use" shall also apply to those capitalized terms used herein that are in the plural or in any tense or variant of the term "Use", such as "Uses", "Using" and "Used".

2.0 POLICY AND PROCEDURES

2.1 Data Receipt and Maintenance by CSHP

2.1.1. CSHP shall comply with all applicable federal and state laws and regulations governing the privacy and security of Personally Identifiable Information, as defined above.

2.1.2. CSHP shall receive and maintain Publicly Supported Programs Data sets that: (a) advance the purposes of the iPHD Project law; (b) adhere to the iPHD Acceptable Use Guidelines; (c) meet the research standards established by the iPHD Governing Board; and (d) are approved by the Partner Agency contributing each specific dataset.

2.1.3. CSHP shall seek to receive, maintain, and transmit De-identified Data whenever possible, and shall only receive, maintain, and transmit Personally Identifiable Information if permitted by applicable law and if the information is in a form and format that are secured to prevent disclosure of Personally Identifiable Information.

2.1.4. In addition to receiving and maintaining Publicly Supported Programs Data, the CSHP may receive and maintain data that are generally available to the public, including, but not limited to, Census demographic data, in accordance with the iPHD Acceptable Use Guidelines and when necessary to advance the purpose of the iPHD Project.

2.1.5. CSHP shall retain Publicly Supported Program Data for the longer of: a) the minimum retention period required by applicable federal and state laws; or b) the time required pursuant to the applicable Business Associate Agreement or Data Use Agreement with the Partner Agency that is providing the data (the "Data Retention Period"). In accordance with the terms of the Business Associate Agreement or Data Use Agreement, at the end of the Data Retention Period, Publicly Supported Program Data shall be returned to the Partner Agency, destroyed, or, if return or destruction is infeasible as agreed to by the Partner Agency, maintained by CSHP, and maintained, Used or Disclosed in accordance with the terms of the applicable agreement.

2.1.6. CSHP shall maintain an up-to-date inventory of all data received and maintained by the iPHD Project, and shall make that inventory publicly available. The inventory shall include, but may not be limited to, information about the data source, summary of data contents, linkages

to other data, date received and, when applicable, date destroyed or returned to the data source.

2.1.7 Data within the iPHD Project may be managed and maintained only by CSHP personnel authorized by the CSHP director. CSHP shall report a list of authorized personnel, their qualifications, and their assigned duties to the iPHD Governing Board, at a minimum on a quarterly basis.

2.1.8 Any unauthorized Use or Disclosure of iPHD Data or other Breach or Security Incident, as defined above, shall be reported in writing to CSHP in accordance with the DUA. CSHP then shall convey any such reports to any Partner Agencies or funders as required by a grant, contract, Business Associate Agreement, Data Use Agreement, and/or Institutional Review Board. Any such unauthorized acquisition, Access, Use, or Disclosure shall be deemed a Breach unless, in accordance with the terms of the applicable Business Associate Agreement or Data Use Agreement, the iPHD Partner Agency or third party to such Business Associate Agreement or DUA determines that there is a low probability that the Protected Health Information or Personally Identifiable Information has been compromised based on a risk assessment of at least the following factors: (i) the nature and extent of the Protected Health Information or Personally Identifiable Information involved, including the types of identifiers and the likelihood of re-identification; (ii) the unauthorized person who Used the Protected Health Information or Personally Identifiable Information or to whom the Disclosure was made; (iii) whether the Protected Health Information or Personally Identifiable Information was actually acquired or viewed; and (iv) the extent to which the risk to the Protected Health Information or Personally Identifiable Information has been mitigated.

2.2 Data Requests, Authorization, and Provision of Data to Authorized Data Users

2.2.1 Applicants for authorized use of iPHD data must complete an application for data Use as established by the iPHD Governing Board**.** The iPHD Project shall make public on its website all application forms, fee schedules, and procedures.

2.2.2 CSHP may provide access to data held by the iPHD Project only when all of the following criteria are met:

2.2.2.1. The entity seeking data access has completed an application and paid applicable fees (set forth in 2.2.1);

2.2.2.2. The iPHD Research Advisory Committee, has reviewed the application and provided advice to the iPHD Governing Board about the: (a) research qualifications of the applicant, (b) validity of the proposed research methods, and (c) alignment of the application with the approved Research Priorities;

2.2.2.3 The iPHD Governing Board has determined that data access is permissible under the iPHD's Acceptable Use Guidelines and consistent with research standards;

2.2.2.4 Release is permissible under terms of Data Use Agreements with applicable iPHD Partner Agencies;

2.2.2.5 All required iPHD Data Use Agreements have been executed by the Authorized Data User and Rutgers (on behalf of CSHP), and Partner Agencies; and

2.2.2.6 All required IRB reviews have been completed, approvals obtained, and documentation thereof submitted to CSHP.

2.2.3 CSHP will not permit access to data that violates any applicable federal or state laws.

2.3 Authorized Data User Compliance

2.3.1 CSHP may produce and release to applicants information about the size of populations or number of events represented in a dataset held by the iPHD Project for the purpose of determining the feasibility of proposed analyses of iPHD data. Only frequency counts that cannot be used to re-identify any individual may be released.

2.3.2 Authorized Data Users of iPHD data shall be subject to fees set forth in a fee schedule that is approved by the iPHD Governing Board to cover the costs of administration of the iPHD Project, application review, data preparation, provision of data, and related costs. The fee schedule shall be derived using methods consistent with NIH "Core Facilities" guidance.[1]

2.3.3 A Partner Agency shall, upon written request, be provided access to data it has submitted to the iPHD Project, so long as those data are not linked to other confidential data. The Partner Agency shall be

[1] FAQs for Costing of NIH-Funded Core Facilities, NIH Notice Number: NOT-OD-13-053. Available at: https://grants.nih.gov/grants/guide/notice-files/not-od-13-053.html

subject to fees, solely to cover the costs of data cleaning or other enhancements to the Partner Agency data.

2.3.4 CSHP may submit an application for data through the iPHD Project, subject to the same fees and review process as other applicants, with conflict rules applying pursuant to Section 2.8 of the iPHD Project By-Laws.

2.3.5 Following approval of an application for data, as described in this Section, CSHP shall provide access to the approved data. Approved data may be provided as De-identified Aggregated Data or as a HIPAA-compliant Limited Data Set pursuant to 45 C.F.R. § 164.514(e) (2), as amended, and as described in the iPHD Acceptable Use Guidelines. All data shall be transmitted securely.

2.3.6 All reports, publications, and other public presentations of statistical data derived from iPHD data must adhere to iPHD Acceptable Use Guidelines to assure individual privacy and confidentiality. Authorized Data Users shall agree to maintain and use the data only in adherence with the approved use. Under no circumstances may Authorized Data Users Disclose Personally Identifiable Information or Statistically Identifiable Data, as defined above that may result in any individual being identified. The Authorized Data User shall be responsible for adhering to all applicable federal and state laws governing data use and privacy of individuals, including but not limited to, HIPAA and 42 CFR Part 2, as it has or will be amended, as well as the provisions of any applicable DUAs and the conditions of IRB approval.

2.3.7 Authorized Data Users engaged in research must make good faith efforts to consult with subject matter experts to advance their understanding and interpretation of the iPHD data approved for use by the Project.

2.3.8 CSHP shall assign specific start and end dates to each approved project that are consistent with all applicable Data Use Agreement(s). No re-use of the data, beyond the approved application, is permitted; although an Authorized Data User may submit a new application for use of the data as described in Section 2.2.2.

2.3.9 Authorized Data Users shall submit a written report to the iPHD Project within 30 days following the end of each project year. The

iPHD Project shall provide guidance on the content of the annual reports, which will include, but may not be limited to: (a) certification by the project principal investigator that all uses of the data are in accordance with the approved project and all applicable data sharing and use agreements and IRB approvals; (b) a brief summary of project findings; (c) a bibliography of all reports, publications, and presentations under development and made using iPHD data; and (d) copies of all publications, reports, and presentations. Submitted materials will be made available to the iPHD Governing Board. Further, all portions of the annual report shall be made public except where such release would violate prior-publication restrictions of materials submitted for peer-reviewed publication or would otherwise violate copyrights. It is the responsibility of the Authorized Data Users to notify CSHP when any materials are subject to non-disclosure due to peer-review or copyright restrictions.