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Date Approved by Board of Health: 1/8/19

Document Title: Protocol for Use and Release of Public Health Surveillance Data [A supplement to the Meigs County Health Dept.'s Health Insurance Portability and Accountability Act (HIPAA)]

Contact: Courtney C. Midkiff, BSC, Administrator/Designated Privacy Officer

Purpose: Public Health Accreditation Board (PHAB) Standard/Measure: 1.2.1 #2 - *The health department must provide written processes and/or protocols that (1) specify which surveillance data are, and which are not, considered to be confidential and (2) assure that confidential data are maintained and handled in a secure and confidential manner.*

Definition:
Public health surveillance is the continuous, systematic collection, analysis and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice. Such surveillance can: serve as an early warning system for impending public health emergencies; document the impact of an intervention, or track progress towards specified goals; and monitor and clarify the epidemiology of health problems, to allow priorities to be set and to inform public health policy and strategies.

Public Health and HIPAA {45 CFR 164.512(b)}
Background:
The MCHD is a covered entity under HIPAA. It also is a public health authority and provider. All are terms used throughout the protocol.

The HIPAA Privacy Rule recognizes the legitimate need for public health authorities and others responsible for ensuring public health and safety to have access to protected health information to carry out their public health mission. The Rule also recognizes that public health reports made by covered entities are an important means of identifying threats to the health and safety of the public at large, as well as individuals. Accordingly, the Rule permits covered entities to disclose protected health information without authorization for specified public health purposes. In addition, if a covered entity engages a business associate to assist in a specified public health activity, the business associate's written agreement with the covered entity should identify these activities, and the business associate may make the disclosure for public health reasons in accordance with its written agreement. (Reference MCHD HIPPA Policy concerning Business Associates.)

Public health practice and research, including such traditional public health activities as program operations, public health surveillance, program evaluation, terrorism preparedness, outbreak investigations, direct health services, and public health research, use PHI to identify, monitor, and respond to disease, death, and disability among

populations. Public health authorities have a long history of protecting and preserving the confidentiality of individually identifiable health information. They also recognize the importance of protecting individual privacy and respecting individual dignity to maintaining the quality and integrity of health data. Centers for Disease Control (CDC) and others have worked to consistently strengthen federal and state public health information privacy practices and legal protections.

Dept. of Health and Human Services (DHHS) recognized the importance of sharing Protected Health Information (PHI) to accomplish essential public health objectives and to meet certain other societal needs (e.g., administration of justice and law enforcement). Therefore, the Privacy Rule expressly permits PHI to be shared for specified public health purposes. For example, covered entities may disclose PHI, without individual authorization, to a public health authority legally authorized to collect or receive the information for the purpose of preventing or controlling disease, injury, or disability [45 CFR § 164.512(b)] (Box 1). Further, the Privacy Rule permits covered entities to make disclosures that are required by other laws, including laws that require disclosures for public health purposes.

Thus, the Privacy Rule provides for the continued functioning of the U.S public health system. Covered entities should become fully aware of the scope of permissible disclosures for public health activities as well as state and local reporting laws and regulations. Moreover, a public health authority may also be a covered entity. For example, a public health agency that operates a health clinic, providing essential health-care services and performing covered transactions electronically, is a covered entity.

How the Rule Works

General Public Health Activities. The Privacy Rule permits covered entities to disclose protected health information, without authorization, to public health authorities who are legally authorized to receive such reports for the purpose of preventing or controlling disease, injury, or disability. This would include, for example, the reporting of a disease or injury; reporting vital events, such as births or deaths; and conducting public health surveillance, investigations, or interventions. See 45 CFR 164.512(b)(1)(i). Also, covered entities may, at the direction of a public health authority, disclose protected health information to a foreign government agency that is acting in collaboration with a public health authority. See 45 CFR 164.512(b)(1)(i). Covered entities who are also a public health authority may use, as well as disclose, protected health information for these public health purposes. See 45 CFR 164.512(b)(2).

A "public health authority" is an agency or authority of the United States government, a State, a territory, a political subdivision of a State or territory, or Indian tribe that is responsible for public health matters as part of its official mandate, as well as a person or entity acting under a grant of authority from, or under a contract with, a public health agency. See 45 CFR 164.501. Examples of a public health authority include State and local health departments, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention, and the Occupational Safety and Health Administration (OSHA). Generally, covered entities are required reasonably to limit the protected health information disclosed for public health purposes to the minimum amount necessary to

accomplish the public health purpose. However, covered entities are not required to make a minimum necessary determination for public health disclosures that are made pursuant to an individual's authorization, or for disclosures that are required by other law. See 45 CFR 164.502(b).

For disclosures to a public health authority, covered entities may reasonably rely on a minimum necessary determination made by the public health authority in requesting the protected health information. See 45 CFR 164.514(d)(3)(iii)(A). For routine and recurring public health disclosures, the MCHD developed standard protocols, as part of their minimum necessary policies and procedures, that address the types and amount of protected health information that may be disclosed for such purposes. See 45 CFR 164.514(d)(3)(i).

Disclosures for Public Health Purposes

The Provider may Use or Disclose PHI for public health activities for certain purposes to (1) a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority; (2) a public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect; (3) a person subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-related product or activity (such as collecting or reporting adverse events, product defects or problems, or biological product deviations; tracking FDA-regulated products; enabling product recalls, repairs, or replacement, or lookback; or conducting post marketing surveillance); (4) a person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition, if the Provider or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation; (5) an employer, about an individual who is a member of the workforce of the employer, if (a) the Provider is a covered health care provider who provides health care to the individual at the request of the employer to conduct an evaluation relating to medical surveillance of the workplace, or to evaluate whether the individual has a work-related illness or injury; (b) the PHI that is Disclosed consists of findings concerning a work-related medical surveillance; (c) the employer needs such findings in order to comply with its obligations, under 29CFR parts 1904 through 1928, 30 CFR parts 50 through 90, or under state law having a similar purpose, to record such illness or injury or to carry out responsibilities for work-place medical surveillance; and (d) the Provider provides written notice to the individual that PHI relating to the medical surveillance of the workplace and work-related illnesses and injuries is disclosed to the employer by giving a copy of the notice to the individual at the time the health care is provided, or if the health care is provided on the work site of the employer, by posting the notice in a prominent place at the location where the health care is provided; and (6) a school, about an individual who is a student or prospective student of the school, if: (a) the PHI that is Disclosed is limited to proof of immunization; (b) the school is required by state or other law to have such proof of immunization prior

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to admitting the individual; and (c) the Provider obtains and documents the agreement to the Disclosure from either: (i) a parent, guardian, or other person acting in loco parentis of the individual, if the individual is an unemancipated minor, or (ii) the individual, if the individual is an adult or emancipated minor. To a Health Oversight Agency for Health Oversight Activities. The Provider may Disclose PHI to a health oversight agency for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of: (1) the health care system;(2) government benefit programs for which health information is relevant to beneficiary eligibility; (3)entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or (4) entities subject to civil rights laws for which health information is necessary for determining compliance. A health oversight activity does not include an investigation or other activity in which the individual is the subject of the investigation or activity and such investigation or other activity does not arise out of and is not directly related to: (1) the receipt of healthcare; (2) a claim for public benefits related to health; or (3) qualification for, or receipt of, public benefits or services when a patient's health is integral to the claim for public benefits or services. Nonetheless, if a health oversight activity or investigation is conducted in conjunction with an oversight activity or investigation relating to a claim for public benefits not related to health, the joint activity or investigation is considered a health oversight activity.

The Privacy Rule allows covered entities to disclose PHI to public health authorities when required by federal, tribal, state, or local laws [45 CFR 164.512(a)]. This includes state laws (or state procedures established under such law) that provide for receiving reporting of disease or injury, child abuse, birth, or death, or conducting public health surveillance, investigation, or intervention.

For disclosures not required by law, covered entities may still disclose, without authorization, to a public health authority authorized by law to collect or receive the information for the purpose of preventing or controlling disease, injury, or disability, the minimum necessary information to accomplish the intended public health purpose of the disclosure [45 CFR 164.512 (b)].

For example, to protect the health of the public, public health officials might need to obtain information related to persons affected by a disease. In certain cases, they might need to contact those affected to determine the cause of the disease to allow for actions to prevent further illness. The Privacy Rule continues to allow for the existing practice of sharing PHI with public health authorities who are authorized by law to collect or receive such information to aid them in their mission of protecting the health of the public. Examples of such activities include those directed at the reporting of disease or injury, reporting adverse events, reporting births and deaths, and investigating the occurrence and cause of injury and disease.

Although it is not a defined term, DHHS interpreted the phrase "authorized by law" to mean that a legal basis exists for the activity. Further, DHHS called the phrase "a term of art," including both actions that are permitted and actions that are required by law [64 FR 59929, November 3, 1999]. This does not mean a public health

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authority at the federal, tribal, state, or local level must have multiple disease or condition-specific laws that authorize each collection of information. Public health authorities operate under broad mandates to protect the health of their constituent populations.

Other Public Health Activities. The Privacy Rule recognizes the important role that persons or entities other than public health authorities play in certain essential public health activities. Accordingly, the Rule permits covered entities to disclose protected health information, without authorization, to such persons or entities for the public health activities discussed below.

1. Child abuse or neglect. Covered entities may disclose protected health information to report known or suspected child abuse or neglect, if the report is made to a public health authority or other appropriate government authority that is authorized by law to receive such reports. For instance, the social services department of a local government might have legal authority to receive reports of child abuse or neglect, in which case, the Privacy Rule would permit a covered entity to report such cases to that authority without obtaining individual authorization. Likewise, a covered entity could report such cases to the police department when the police department is authorized by law to receive such reports. See 45 CFR 164.512(b)(1)(ii). See also 45 CFR 512(c) for information regarding disclosures about adult victims of abuse, neglect, or domestic violence.
2. Quality, safety or effectiveness of a product or activity regulated by the FDA. Covered entities may disclose protected health information to a person subject to FDA jurisdiction, for public health purposes related to the quality, safety or effectiveness of an FDA-regulated product or activity for which that person has responsibility. Examples of purposes or activities for which such disclosures may be made include, but are not limited to:
    a. Collecting or reporting adverse events (including similar reports regarding food and dietary supplements), product defects or problems (including problems regarding use or labeling), or biological product deviations;
    b. Tracking FDA-regulated products;
    c. Enabling product recalls, repairs, replacement or lookback (which includes locating and notifying individuals who received recalled or withdrawn products or products that are the subject of lookback); and
    d. Conducting post-marketing surveillance. See 45 CFR 164.512(b)(1)(iii). The "person" subject to the jurisdiction of the FDA does not have to be a specific individual. Rather, it can be an individual or an entity, such as a partnership, corporation, or association. Covered entities may identify the party or parties responsible for an FDA-regulated product from the product label, from written material that accompanies the product (known as labeling), or from sources of labeling, such as the Physician's Desk Reference.
    e. Persons at risk of contracting or spreading a disease. A covered entity may disclose protected health information to a person who is at risk of contracting or spreading a disease or condition if other law authorizes the covered entity to notify such individuals as necessary to carry out public health

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interventions or investigations. For example, a covered health care provider may disclose protected health information as needed to notify a person that (s)he has been exposed to a communicable disease if the covered entity is legally authorized to do so to prevent or control the spread of the disease. See 45 CFR 164.512(b)(1)(iv).

3. Workplace medical surveillance. A covered health care provider who provides a health care service to an individual at the request of the individual's employer, or provides the service in the capacity of a member of the employer's workforce, may disclose the individual's protected health information to the employer for the purposes of workplace medical surveillance or the evaluation of work-related illness and injuries to the extent the employer needs that information to comply with OSHA, the Mine Safety and Health Administration (MSHA), or the requirements of State laws having a similar purpose. The information disclosed must be limited to the provider's findings regarding such medical surveillance or work-related illness or injury. The covered health care provider must provide the individual with written notice that the information will be disclosed to his or her employer (or the notice may be posted at the worksite if that is where the service is provided). See 45 CFR 164.512(b)(1)(v).

Protocol for Requests

1. Routine and Recurring Requests. The Privacy Official (or an Employee at the Privacy Official's direction) shall create and maintain a file of routine and recurring requests which identifies the information that is necessary for the purpose of the requested Disclosure and create a policy that limits the PHI requested to the amount reasonably necessary to accomplish the purpose for which the request is made.

2. For all other requests for PHI, contact the Privacy Official, who will (1) ensure that the PHI requested is limited to the information reasonably necessary to accomplish the purpose for which the request is made and (2) review requests for Disclosure on an individual basis in accordance with such criteria.

3. Do not request an entire medical record, except when the entire medical record is specifically justified as the amount that is reasonably necessary to accomplish the purpose of the request.

Exceptions

The "minimum-necessary" standard does not apply to any of the following:

- Disclosures to or requests by a health care provider for Treatment;
- Uses or Disclosures made to the individual;
- Uses or Disclosures made pursuant to a valid authorization;
- Disclosures made to the Secretary;
- Uses or Disclosures required by law; and
- Uses or Disclosures required to comply with HIPAA.

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Documentation

Employees shall maintain copies of all of the following items for a period of at least six years (unless state or federal law mandates a different time period) from the date the documents were created or were last in effect, whichever is later:

a. "Notices of Privacy Practices" that are issued;
b. Copies of policies and procedures;
c. Individual authorizations;
d. When Disclosures of certain PHI are made:
   - the date of the Disclosure;
   - the name of the entity or persons who received the PHI and, if known, the address of such entity or person;
   - a brief description of the PHI Disclosed;
   - a brief statement of the purpose of the Disclosure;
e. Breaches of Unsecured PHI and notices related to any such Breaches;
f. All sanctions that are applied

Verification of Identity of Those Requesting Protected Health Information.

Employees must take steps to verify the identity of individuals who request access to PHI. They must also verify the authority of any person to have access to PHI, if the identity or authority of such person is not known. Separate procedures are set forth below for verifying the identity and authority, depending on whether the request is made by the individual, a parent seeking access to the PHI of his or her unemancipated minor child, a personal representative, or a public official seeking access.

1. In General: Except for certain Disclosures related to an involvement with an individual's care and certain notification purposes, prior to any Disclosure permitted by these Privacy Procedures and the Provider's Privacy Policy, the Provider must (1) verify the identity of a person requesting PHI and the authority of any such person to have access to PHI, if the identity of any such authority of such person is not known to the Provider; and (2) obtain any documentation, statements, or representations, whether oral or written, from the person requesting the PHI when such documentation, statement, or representation is a condition of the Disclosure under the HIPAA privacy rules. If a Disclosure is conditioned by the HIPAA privacy rules on particular documentation, statements, or representations from the person requesting the PHI, the Provider may rely, if such reliance is reasonable under the circumstances, on documentation, statements or representations that, on their face, meet the applicable requirements. With respect to Disclosures permitted by law pursuant to an administrative request, the administrative subpoena or similar process or by a written statement that, on its face, demonstrates

that the applicable requirements have been met. With respect to certain Disclosures related to research purposes, the Privacy Official shall contact the Provider's legal counsel or otherwise ensure compliance with the privacy rules (including 45 C.F.R. §164.512(i), §164.514, and §164.524(a)(2)(iii)) to determine whether the verification requirements have been met.

2. Request Made by Public Official. If a public official (or person acting on behalf of a public official) requests access to PHI, and if the request is for one of the purposes set forth above in "Mandatory Disclosures of PHI: to Individuals and Department of Health and Human Services" or "Permissive Uses and Disclosures of PHI: As Required By Law for Legal and Public Policy Purposes", the following steps should be followed to verify the official's identity and authority:

a. If the request is made in person, request presentation of an agency identification badge, other official credentials, or other proof of government status. Make a copy of the identification provided and file it with the individual's Designated Record Set.

b. If the request is in writing, verify that the request is on the appropriate government letterhead; If the request is made by a person purporting to act on behalf of a public official, request a written statement on appropriate government letterhead that the person is acting under the government's authority or other evidence or documentation of agency, such as a contract for services, memorandum of understanding, or purchase order, that establishes that the person is acting on behalf of the public official.

c. Request a written statement of the legal authority under which the information is requested, or, if a written statement would be impracticable, an oral statement of such legal authority. If the request is made pursuant to legal process, warrant, subpoena, order, or other legal process issued by a grand jury or a judicial or administrative tribunal, contact the legal department of the Provider or retain outside counsel for additional guidance.

d. Obtain approval for the Disclosure from the Privacy Official.

e. When making certain Disclosures of PHI related an involvement with an individual's care and certain notification purposes, the Privacy Official shall exercise professional judgment in making such Disclosure to ensure compliance with the HIPAA privacy rules. When making certain Disclosures of PHI to avert a serious threat to health or safety, the Privacy Official shall only make a Disclosure based upon a good faith belief that Disclosure is in compliance with the HIPAA privacy rules. Disclosures must be documented in accordance with the MCHD HIPAA Policy.

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Complying With the "Minimum-Necessary" Standard: Procedures for Uses

1. The Privacy Official (or an Employee at the Privacy Official's direction) shall create and maintain a file of Employees or classes of Employees who need access to PHI to carry out their duties, the categories of PHI to which access is needed, and any conditions appropriate to such access.

2. Do not Use an entire medical record, except when the entire medical record is specifically justified as the amount that is reasonably necessary to accomplish the purpose of the Use.

Procedures for Disclosures

3. Routine and Recurring Disclosures. The Privacy Official (or an Employee at the Privacy Official's direction) shall create and maintain a file of routine and recurring Disclosures which identifies the types of PHI to be Disclosed, the types of person who may receive the PHI, the conditions that would apply to such access, and the standards for Disclosure to routinely-hired types of Business Associates.

4. The Privacy Official shall also create a policy for each specific recurring Disclosure that limits the PHI Disclosed to the amount reasonably necessary to achieve the purpose of the Disclosure.

5. For all other requests for Disclosures of PHI, contact the Privacy Official, who will (1) ensure that the PHI Disclosed is limited to the information reasonably necessary to accomplish the purpose for which the Disclosure is sought, and (2) review the requests for Disclosure on an individual basis in accordance with such criteria.

6. The Provider may rely, if such reliance is reasonable under the circumstances, on a requested Disclosure as the minimum necessary for the stated purpose when: (1) making Disclosures to public officials that are permitted under the HIPAA privacy rules, if the public official represents that the information requested is the minimum necessary for the stated purposes; (2) the information is requested by another covered entity; (3) the information is requested by a professional who is a member of its workforce or is a Business Associate of the Provider for the purpose of providing professional services to the Provider, if the professional represents that the information requested is the minimum necessary for the stated purposes; or (4) documentation or representations that comply with the applicable requirements of the HIPAA privacy rules have been provided by a person requesting the information for research purposes.

7. Do not disclose an entire medical record, except when the entire medical record is specifically justified as the amount that is reasonably necessary to accomplish the purpose of the Disclosure

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De-Identified Information

De-identified data (e.g., aggregate statistical data or data stripped of individual identifiers) require no individual privacy protections and are not covered by the Privacy Rule. De-identifying can be conducted through statistical de-identification --- a properly qualified statistician using accepted analytic techniques concludes the risk is substantially limited that the information might be used, alone or in combination with other reasonably available information, to identify the subject of the information [45 CFR § 164.514(b)]; or the safe-harbor method --- a covered entity or its business associate de-identifies information by removing 18 identifiers and the covered entity does not have actual knowledge that the remaining information can be used alone or in combination with other data to identify the subject [45 CFR § 164.514(b)]. In certain instances, working with de-identified data may have limited value to clinical research and other activities. When that is the case, a limited data set may be useful.

Disclosures of De-Identified Information

1. Obtain approval from Privacy Official for the Disclosure. The Privacy Official will verify that the information is de-identified.

2. The Provider may freely Use and Disclose De-identified Information. De-identified Information is not PHI.

Limited Data Sets

Health information in a limited data set is not directly identifiable, but may contain more identifiers than de-identified data that has been stripped of the 18 identifiers [45 CFR § 164.514] (Box 3). A data-use agreement must establish who is permitted to use or receive the limited data set, and provide that the recipient will not use or disclose the information other than as permitted by the agreement or as otherwise required by law; use appropriate safeguards to prevent uses or disclosures of the information that are inconsistent with the data-use agreement; report to the covered entity any use or disclosure of the information, in violation of the agreement, of which it becomes aware; ensure that any agents to whom it provides the limited data set agree to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and not attempt to re-identify the information or contact the individual.

Protocol for Limited Data Set Uses and Disclosures

Under limited circumstances, the Provider may Use or Disclose a Limited Data Set, if the Provider enters into a data use agreement with the Limited Data Set recipient. An Employee shall contact the Privacy Official prior to Using or Disclosing such information. The Privacy Official shall contact the Provider's legal counsel or otherwise ensure compliance with 45 C.F.R. §164.514(e) prior to Using or Disclosing a Limited Data Set.

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The Privacy Rule and Public Health Research

The MCHD is often asked to participate in research projects. In addition, PHAB Domain 10 requires local health department participation in and with such efforts.

The topic of research under the Privacy Rule is covered in depth in the DHHS report, Protecting Personal Health Information in Research --- Understanding the HIPAA Privacy Rule. The Privacy Rule provides separate provisions for disclosure without individual authorization for public health purposes and for certain research [45 CFR § 164.512(b)] [45 CFR § 164.512(i)]. Other federal law pertaining to research stresses the importance of distinguishing between research and practice to ensure that human subjects are appropriately protected [45 CFR Part 46]. For certain activities, this distinction is not always clear. A full discussion of the distinctions between public health practice and research is beyond the scope of this document. However, CDC and others provide guidance in this area.

Research Versus Practice

The definition of research is the same for the Privacy Rule and the Common Rule (10) --- systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Research is designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge. The majority of public health activities (e.g., public health surveillance, and disease prevention and control projects) are based on scientific evidence and data collection or analytic methods similar to those used in research. However, they are not designed to contribute to generalizable knowledge. Their primary purpose is to protect the health of the population through such activities as disease surveillance, prevention, or control.

The Belmont Report defines practice as interventions designed solely to enhance the well-being of a person, patient, or client, and which have reasonable expectation of success. The report further states that the purpose of medical or behavioral practice is to provide diagnosis, preventive treatment, or therapy to particular patients. For public health agencies, the patient is the community. Public health practice activities (e.g., public health surveillance, disease control, or program evaluation) are undertaken with the intent to benefit a specific community, although occasionally they may provide unintended generalizable benefits to others.

Some public health activities that are initially public health practice may subsequently evolve into a research activity (e.g., an investigation to determine the cause of an outbreak that incorporates a research study evaluating the efficacy of a new drug to treat the illness). When that is the case, the disclosures may be made initially under the public health provisions of the Privacy Rule. But when the activity becomes an ongoing research activity, the entity should consider application of the relevant research disclosures provisions to continue to obtain information for this purpose. Moreover, there may be cases where the activity is both research and public health practice (e.g.,

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an ongoing survey to monitor health conditions in the population, data from which can also be analyzed for research purposes). In those cases, disclosures may be made either under the research provisions or the public health provisions, as appropriate --- the covered entity need not comply with both sets of requirements.

Signed:

Marc Barr, Health Commissioner

Roger Gaul, Board of Health President