World Privacy Forum

The Precision Medicine Initiative and Privacy: Will Any Legal Protections Apply?

By Robert Gellman and Pam Dixon

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Brief Summary of Report

This report reviews privacy law applicable to the Precision Medicine Initiative (PMI), and the large medical information and biospecimen database at its center. Precision medicine approaches to disease seek to incorporate individual variability in genes, environment, and lifestyle in research to eventually reach the goal of maximizing treatment effectiveness for individuals. The PMI will include a robust genetic research component. The HIPAA health privacy rule and its protections for individuals will not apply to PMI research activities. Other privacy laws may apply, such as the Privacy Act of 1974, but there is uncertainty regarding if or how this and other laws apply. The PMI offers a set of privacy guidelines, but the guidelines lack detail and fail to address underlying legal requirements and protections.

The key privacy concerns raised by the PMI are the lack of applicable law to govern its collection and use of individuals' health data, the potential waiver of the patient-physician legal privilege that can shield data from disclosure through litigation, and the possibility of law enforcement access to patient records held in the PMI. Before it launches, the PMI needs to clarify the legal and administrative privacy protections that apply to its activities. People who volunteer their medical data and biospecimens must be told what specific legal protections apply and do not apply.

About the Authors

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About the World Privacy Forum

The World Privacy Forum is a non-profit public interest research and consumer education group that focuses on the research and analysis of privacy-related issues. Founded in 2003, the Forum publishes significant privacy research and policy studies on health privacy, privacy self-regulation, financial privacy and identity issues, biometrics, and data broker privacy practices among other issues. www.worldprivacyforum.org.

Contents

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Introduction and Summary

Medical treatments tailored to each individual's physiology and genetic history have long been a dream. The most current iteration of turning personalized medicine into a reality is President Obama's Precision Medicine Initiative (PMI), an ambitious program with a goal of gathering the freely volunteered health and biospecimen data of over a million people to facilitate research to bring that dream closer to reality. The research envisioned after PMI is operational will focus on disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle.

The goals of the initiative are laudable, but many core privacy questions remain unanswered. These unanswered questions may undercut individuals' willingness to share their data and may create new problems for volunteers. As with many healthcare research activities, some see privacy as an obstacle to scientific advancement. That objection fails to recognize privacy's essential value in and to the health care system. Privacy, rather than being an impediment to medical research, is an essential feature of health care and medical research. Privacy must be addressed in any major health care data activity. If the PMI does not clarify the privacy protections for its activities, individuals will be more reluctant to volunteer to participate.

The initiative is nearing its launch point with a goal of collecting the health records and biospecimens of one million volunteers.[1] (See Appendices A and B in this report for specifics on the PMI timeline, and what information is to be collected from participants.) The National Institutes of Health materials, including a Frequently Asked Questions, and other materials describing what volunteers can expect, discusses briefly how privacy will be handled. Yet despite this, an individual considering participation and privacy experts who advocate on their behalf cannot tell how the initiative will be structured, who will hold the data, and how or whether privacy concerns will be addressed adequately.

This document analyzes the published plans for the initiative, raises questions about how the PMI plans to address privacy, and considers in brief the implications for volunteers. Many details about the PMI are still unknown. The analysis and discussion here reflects current privacy law, which is a known commodity and not likely to change in the near future.

The goal of this paper is to make public the legal analysis undergirding our privacy concerns, and to identify issues that the PMI should address in the near future.

Key Findings:

- Medical record data and biospecimen data that consumers donate to the PMI are not covered by the core federal health privacy law while in the hands of the PMI. The health privacy rule issued under the authority of the Health Insurance Portability and Accountability Act (HIPAA) does not apply to the PMI and will not apply to most research activities conducted using information available from the PMI.

- Consumers may have no formal legal right to obtain their own information from the PMI unless a US government agency administers the PMI, something that is not expected. The Privacy Act of 1974, which provides citizens with the ability to review data collected about them by a government agency, applies only if a federal agency operates the PMI. We do not yet know with certainty if a federal agency will operate any part of the PMI. However, if a federal agency operates the PMI, the Privacy Act's disclosure provisions allow agencies considerable authority to disclose records subject to the Act and to define new categories of disclosures at any time through new rules. In particular, the Act allows many types of disclosure to foreign, national, state, and local law enforcement agencies with few procedural prerequisites. We do not yet know what disclosure authority will apply to PMI records or even if they are subject to the Privacy Act. (See Appendix C.)

- Patients who share their health records and biospecimens with the PMI could lose the ability to claim a physician-patient privilege in unrelated judicial proceedings.

[1] The Precision Medicine Initiative Cohort Program – Building a Research Fpundation for 21st Century Medicine, Sept. 17, 2015. PMI Working Report to the Advisory Committee to the Director, NIH, p. 1. https://www.nih.gov/sites/default/files/research-training/initiatives/pmi/pmi-working-group-report-20150917-2.pdf.

- A limited amount of patient records shared with PMI may be protected from subsequent disclosure if 42 C.F.R. Part 2 (rules governing substance abuse records) applied to the records at their original source. If so, records disclosed to the PMI from health care providers subject to the substance abuse privacy rules would retain their confidentiality if disclosed to the PMI. This may be the only existing privacy law applicable to the PMI, although it would cover few of the health records in the PMI.

- Certificates of confidentiality for research activities available through the Department of Health and Human Services may offer some legal protections for research records, but there are many uncertainties about the scope and value of the certificates. There are known limitations about the protections this would offer.

- When volunteers enroll in the PMI, they donate a great deal of personal information in the form of medical records and biospecimens. However, cell phone data monitoring, social media monitoring, sensor monitoring and other real-time monitoring are under discussion. How the privacy of the real time systems will be handled is an unknown. Further administrative records about volunteers – as opposed to health information – may be extensive and presents their own privacy concerns. Administrative records may include contact information, identification numbers, employment and educational history, location data, and more.

Key Recommendations:

1. The PMI needs to detail its structure and organization with clarity so that the privacy protections or lack of privacy protections for its records can be assessed. The public needs to know what institutions will maintain information in the PMI and where they are located. The PMI must explain how privacy laws, if any, will apply to it. The privacy and security standards issued so far do not answer the questions about what legal protections will apply.

2. The PMI should not begin soliciting information or biospecimens from or about individuals until it clearly describes the applicable privacy protections. The description should include potential uses and disclosures of PMI information for law enforcement and national security purposes. The description of applicable privacy rules should cover health records, administrative records, and any real-time monitoring from mobile or other devices. Volunteers should be told expressly if HIPAA does not apply to the PMI.

3. The E-Government Act of 2002 requires federal agencies to conduct a Privacy Impact Assessment before they develop or procure information technology systems or projects that collect, maintain or disseminate information in identifiable form from or about members of the

public.[2] We have not seen a PIA for the PMI. There is an immediate need for a PIA that includes an opportunity for public comment and debate.

4. If the Privacy Act of 1974 applies to PMI or any significant part of it, then the National Institutes of Health should publish a system of records notice and allow adequate time for public comment.

5. If the Privacy Act of 1974 does not apply to the PMI, then it is possible that no health privacy or other privacy law will apply to most data and biospecimens. As a result, patient data could be vulnerable to a host of unrelated public and private demands and activities. If so, then PMI may need its own privacy law in place before it starts.

Discussion and Legal Analysis of the Precision Medicine Initiative

Background and Purpose of the Precision Medicine Initiative

President Obama announced the Precision Medicine Initiative (PMI) in January 2015. At the time, many hailed the PMI as the beginning of many medical research dreams come true. The core of the program is creating a large national database for medical research consisting of medical records information, survey information, and biospecimens.

According to White House documents:

> The mission of the President's Precision Medicine Initiative (PMI) is to enable a new era of medicine through research, technology, and policies that empower patients, researchers, and providers to work together toward the development of individualized treatments.[3]

To accomplish these goals, the PMI will develop "a voluntary national research cohort of a million or more volunteers to propel our understanding of health and disease and set the

[2] See Office of Management and Budget, Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002 (2003)(M-03-22), https://www.whitehouse.gov/omb/memoranda_m03-22/.
[3] White House, *Precision Medicine Initiative: Data Security Policy Principles and Framework* (Feb. 25, 2016), http://go.wh.gov/Pdm1Li.

foundation for a new way of doing research through engaged participants and open, responsible data sharing."[4]

Volunteers will share a robust data set with the initiative. What we know so far is from the National Institutes of Health, which states:

> What would be expected of me if I enroll in the Precision Medicine Initiative Cohort Program?
>
> Volunteers will be asked to share data including data from their electronic health records and health survey information. Participants may be asked to provide health data on lifestyle habits and environmental exposures as well. Participants will also undergo a standard baseline physical exam and provide a biological sample such as blood, urine, or saliva.[5]

We also know that volunteers may be asked for a great deal of additional information, which may eventually include information from their mobile phones and other sensors, as well as social media and perhaps even records of over the counter drug purchases. (Appendix B.) In this document, we do not question the intent or the goal of the PMI. At present, we accept as a given that the initiative is properly motivated and seeks to achieve an admirable public policy goal using a reasonable approach.

Still, any activity that expects to collect detailed health information and biospecimens from at least a million volunteers requires careful consideration of the privacy consequences. In addition to the health records and biospecimens, the PMI will have administrative records about volunteers that are not themselves health records per se. An administrative record may have identification and contact information for the volunteer, data about sources of information (e.g., physicians, other health care providers, and insurers), data about health devices used by the volunteer, work and education histories, financial information, and possibly more. Administrative information could be held in one or in multiple databases, and the databases could be maintained by different organizations in different locations.

A million administrative records about volunteers present major privacy and security concerns of their own, apart from any substantive health information. How these records will be organized, who will hold the records, and what privacy regime (if any) applies to the administrative records is not clear. It is also not clear if PMI records held in different states will be subject to different state privacy laws.

[4] https://www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative.
[5] NIH FAQ https://www.nih.gov/precision-medicine-initiative-cohort-program/precision-medicine-initiative-cohort-program-frequently-asked-questions .

The White House initiative paid some attention to both privacy and security. For example, White House documents outline privacy and security policies and principles.[6] While many of the principles acknowledge the need to address privacy, the principles are quite general and lack important legal and administrative details. The principles appear to be voluntary and may not create any enforceable legal rights.

One of the transparency principles states:

> Information should be made publicly available concerning PMI data protections and use, and compliance with governance rules.[7]

We applaud this policy, but this principle does not supply the details of those data protections or when they will be available. The statement's use of passive voice only underscores the problem. We do not know who should make information available or who should comply with governance rules. Additionally, many core documents directed to researchers do not address privacy in any meaningful way, instead, focusing on security issues.[8] When dealing with a richly detailed health database, the details matter and the law matters.

The lack of specificity about privacy at this late date is troubling.[9] However, this report focuses only on applicable privacy law. It is extremely important to distinguish between privacy **principles** that are voluntary and perhaps unenforceable on one hand, and actual privacy **law** that has enforceable rights and procedures.

We accept that the PMI has voluntary privacy principles, but we cannot analyze the privacy principles at this time, recognizing that they lack specificity and may not carry the force of law.[10] We do not know how the principles will be made operational. [11]

The issue that we raise in this report is how the PMI will actually protect privacy in detail and what specific laws will apply. In order to discuss this issue, we consider different possible structures for the Initiative and evaluate how existing privacy laws may apply.

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[6] See White House, *Precision Medicine Initiative: Data Security Policy Principles and Framework* (Feb. 25, 2016), http://go.wh.gov/Pdm1Li; *Precision Medicine Initiative: Privacy and Trust Principles* (Nov. 9, 2015), https://www.whitehouse.gov/sites/default/files/microsites/finalpmiprivacyandtrustprinciples.pdf.

[7] *Precision Medicine Initiative: Privacy and Trust Principle*s (Nov. 9, 2015), https://www.whitehouse.gov/sites/default/files/microsites/finalpmiprivacyandtrustprinciples.pdf.

[8] See for example, FAQ for Other Transaction Awards, https://www.nih.gov/precision-medicine-initiative-cohort-program/frequently-asked-questions-other-transaction-awards.

[9] See https://www.nih.gov/sites/default/files/research-training/initiatives/pmi/20151118-ot-award-policy-guide.pdf.

[10] Under the FTC Act §5, the privacy principles could be enforced by the Federal Trade Commission in certain circumstances, for example, when there was an unfair or a deceptive business practice. This type of enforcement is quite different than the affirmative rights conferred to individuals under, for example, HIPAA.

[11] For example, a key PMI funding document does not discuss how to specifically implement the privacy principles. https://www.nih.gov/sites/default/files/research-training/initiatives/pmi/20151116-pmi-pilot-phase-studies-ota-sow.pdf. The document states "All partners in the President's PMI are expected to adhere to the PMI privacy and trust principles developed by the White House" with no substantive elaboration. The Genetic Information Nondiscrimination Act of 2008 is mentioned briefly, but its relevance is uncertain as we do not anticipate that the PMI Cohort Program will not provide genetic information to health insurance companies or employers.

Organizational Structure of the PMI Data and Data Managers

A major organizational decision with profound implications for privacy in the PMI is who will hold the data and biospecimens and take responsibility for privacy. We recognize that there may be multiple databases (for patient data, for specimens, etc.), multiple data controllers, and different management and technical structures for the PMI. For example, the September 2015 report of a PMI Working Group includes this paragraph suggesting a hub-and-spoke model.

> To facilitate data access, data normalization, and participant engagement, the Working Group recommends that the PMI-CP follow a "hub-and-spoke" model that has a Coordinating Center to provide a single point of contact for coordinating data, biospecimens, participant communication and engagement, and research studies. The Working Group encourages NIH to consider novel collaborations with not-for-profit and commercial organizations to achieve state-of-the-art analysis methods, scientific rigor, elastic storage and compute capabilities, and technological expertise. For data storage and access, the Working Group recommends the PMI-CP pursue a hybrid data and analytics architecture that leverages both centralized data storage of core data while preserving federated access to additional data at the nodes across the network, as needed by specific studies. This hybrid model would accelerate execution of many research queries but still allow detailed data access for queries not addressable through the current data common data models.[12]

The current discussions of governance structure can be seen in Appendix C. To make our discussion here manageable, we make a simple assumption that there is a single manager for any PMI database, and that manager has responsibility for establishing privacy standards and for complying with any applicable privacy laws. Further, we assume that the PMI manager may either be a federal agency (e.g., NIH) or a non-federal agency (e.g., a federal contractor or grantee). The NIH has awarded a first round of grants for the PMI, including to Vanderbilt Medical Center for a pilot project.[13]

This discussion reviews the privacy consequences of having a federal or a non-federal manager.

[12] Precision Medicine Initiative (PMI) Working Group Report to the Advisory Committee to the Director, National Institutes of Health, The Precision Medicine Initiative Cohort Program – Building a Research Foundation for 21st Century Medicine 4 (Sep. 17, 2015) (internal cross references omitted), http://acd.od.nih.gov/reports/DRAFT-PMI-WG-Report-9-11-2015-508.pdf.

[13] See "Funded Research" section, https://www.nih.gov/precision-medicine-initiative-cohort-program/funding-opportunities.

HIPAA and the Precision Medicine Initiative: HIPAA Protections Will Not Apply to the PMI

Summary: HIPAA will not protect any data held by the PMI manager or used downstream by researchers.

The HIPAA privacy rule[14] applies to three categories of health care institutions: most health care providers, most health plans (insurers), and health care clearinghouses. These institutions are known as *HIPAA covered entities*. The HIPAA privacy rule does not apply to health information held by others. Thus, the rule does not cover any identifiable health information held by data brokers, websites, credit bureaus, disease registries, health researchers, disease advocacy organizations, law enforcement agencies, or others. This is true even if the information originated with a HIPAA covered entity. Once a HIPAA covered entity shares health information protected under HIPAA with anyone who is not a HIPAA covered entity, the information generally passes outside the scope of the HIPAA privacy rule and beyond the jurisdiction of HIPAA oversight and enforcement. This is true whether a federal agency or a private entity acquires HIPAA protected health information.

The National Institutes of Health and HIPAA

The National Institutes of Health (NIH) is perhaps the only significant health care provider not subject to the HIPAA privacy rule. Why? "NIH does not meet the definition of a 'covered entity' and is therefore not covered by HIPAA because it does not bill third parties for the health care they receive at the Clinical Center." NIH buried this disclosure in a Frequently Asked Questions document from the NIH Senior Counsel for Privacy (March 2013) at page 4, question 16 ("Who can I contact if a person or organization covered by the Privacy Rule violates my health information privacy rights?").[15]

HHS could easily have written the HIPAA privacy rule to cover NIH but chose not to do so. If HIPAA applied to NIH, however, it would probably not matter for the PMI because PMI is not a treatment activity. NIH would almost certainly have defined itself as a *hybrid entity* under HIPAA so that its many non-treatment activities would fall outside of HIPAA. Many health care providers have functions that are not treatment activities. For example, a supermarket may be a hybrid entity, with a pharmacy that is a covered entity and its other activities not subject to HIPAA.[16]

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[14] The Department of Health and Human Services issued the health privacy rule under the authority of the Health Insurance Portability and Accountability Act, Public Law 104-191. There are also HIPAA security and data breach rules, and these rules have the same applicability as the privacy rule. The focus here is only on the privacy rule. See generally http://www.hhs.gov/hipaa/for-professionals/index.html#1954.

[15] National Institutes of Health, Frequently Asked Questions, Question 16 (Match 2013), ("Who can I contact if a person or organization covered by the Privacy Rule violates my health information privacy rights?"). https://oma.od.nih.gov/forms/Privacy Documents/Documents/NIH Privacy FAQs March 2013.pdf.

[16] For more detailed explanations about hybrid entities, see World Privacy Forum, *Patient's Guide to HIPAA, FAQ 9: Which Entities Must Comply with HIPAA?* https://www.worldprivacyforum.org/2013/09/hipaaguide9-2/ . For

Disclosures Allowable under HIPAA

Even if the HIPAA privacy rule applied to the PMI, its protections against disclosures leave much to be desired. For example, the rule allows six broad categories of disclosures of HIPAA protected health information for law enforcement purposes, with the most open-ended allowing disclosures in response to "administrative requests."[17] The rule's standards and procedures for these requests are weak, and a large number of federal, state, and local agencies are law enforcement agencies. The HIPAA provision for national security disclosures is even less restrictive. The rule allows unrestricted disclosures of health information to any national security or intelligence agency. HIPAA imposes no conditions or procedures prior to a national security disclosure. Any HIPAA-covered entity can, without violating HIPAA, disclose any patient information to a national security agency without a court order, without a subpoena, and, remarkably, even without a request from the agency.[18]

Will the Privacy Act of 1974 Protect the PMI Data?

Summary: The Privacy Act of 1974 applies only if a federal agency operates PMI. However, the Act's disclosure provisions allow agencies considerable authority to recognize new disclosures. In particular, the Act allows many types of disclosure to foreign, national, state, and local law enforcement agencies with few procedural prerequisites. We do not yet know what disclosure authority will apply to PMI records under the Privacy Act.

The Privacy Act of 1974[19] applies to federal agencies and some federal contractors. It does not apply to recipients of federal funds, federal grantees, or tax-exempt organizations. Thus, if a non-federal entity operates PMI, that entity is not subject to the Privacy Act of 1974, and the Act offers no protections to data subjects of the PMI.[20] In that case, the Act offers no protections to data subjects of PMI. We underscore that the Privacy Act of 1974 will not apply if NIH uses a

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more on NIH and HIPAA see World Privacy Forum, *Patient's Guide to HIPAA, FAQ 3*: *What Laws are Relevant to Health Privacy*? https://www.worldprivacyforum.org/2013/09/hipaaguide3/ .

[17] 45 C.F.R. § 164.512(f)(1)(ii)(C).

[18] Comments of the World Privacy Forum for the Universal Periodic Review, UN Human Rights Council. *The Right to Health Privacy: Human Rights and the Surveillance and Interception of Medical and Health Records by Security Agencies*, October 14, 2014. http://www.worldprivacyforum.org/wp content/uploads/2014/10/WPF_UPR_UScomments_October2014_fs.pdf.

[19] 5 U.S.C. § 552a.

[20] If a federal agency used a contract to hire a non-federal entity, it is possible that the Privacy Act of 1974 could apply, but only if the contract provided for the maintenance of personal information *to accomplish an agency function*. 5 U.S.C. § 552a(m). However, it is highly unlikely that any federal funds used to support PMI would be conveyed by a contract. It is much more likely that a federal agency would use a grant instrument rather than a contract, and federal grantees are not subject to the Privacy Act of 1974.

grant instrument to fund PMI operations by a third party. Use of a contract rather than a grant does not assure application of the Privacy Act of 1974, and we think that a contract would not bring PMI activities under the Act.[21] We also note that in the currently funded PMI pilot programs the existing agreements appear not to be government contracts that could be subject to the Privacy Act.[22]

The Privacy Act of 1974 has good and bad elements. It implements all elements of Fair Information Practices,[23] but the Act is old and quite out-of-date. While many of its provisions provide useful privacy protections (e.g., access and correction rights, notice, and accountability), the Act's disclosure provisions have been controversial for decades.

If a federal agency maintains any health records for PMI, those records would be subject to the Privacy Act of 1974 provided that 1) the records are under the control of the agency; and 2) the agency retrieves information by name, identifying number, or other identifying particular assigned to the individual.[24] We do not see any loophole in the Privacy Act of 1974 that would allow any agency to maintain PMI health records without complying with the Act. However, if an agency avoided the Privacy Act of 1974 (e.g., by awarding a grant for operation of the PMI) then no general health privacy law would apply at all. All personal records would be usable and disclosable without statutory restrictions whatsoever. Needless to say, we do not see that as a good option.

If the Privacy Act of 1974 applies, however, we can guess how it might work. We assume here that if a federal agency operated PMI, that agency would be the National Institutes of Health. In order to assess how the Privacy Act of 1974 would apply, we can look at existing systems of records that NIH maintains and see how NIH can use and disclose those records.[25] The NIH already has a system of records that bears a lot of similarity to what we might expect for the PMI. That system is *Clinical Research: Candidate Healthy Volunteer Records*.[26] The system contains records on "normally healthy individuals who volunteer to participate in NIH studies."

We focus here on how an agency can use or disclose records for law enforcement purposes. The discussion, perhaps unfortunately, requires a review of the entrails of the Privacy Act. The Act's law enforcement disclosure provisions are better in some ways and worse in some way than the comparable provisions in the HIPAA health privacy rule.

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[21] If a federal agency used a contract to hire a non-federal entity, it is possible that the Privacy Act of 1974 could apply, but only if the contract provided for the maintenance of personal information *to accomplish an agency function*. 5 U.S.C. § 552a(m). However, it is highly unlikely that any federal funds used to support PMI would be conveyed through a contract. It is much more likely that a federal agency would use a grant instrument rather than a contract, and federal grantees are not subject to the Privacy Act of 1974.

[22] https://www.nih.gov/precision-medicine-initiative-cohort-program/frequently-asked-questions-other-transaction-awards.

[23] See generally Robert Gellman, *Fair Information Practices: A Basic History* (Version 2.15, 2015), http://bobgellman.com/rg-docs/rg-FIPshistory.pdf.

[24] See the definition of *system of records* at 5 U.S.C. § 552a(a)(5).

[25] A system of records is a group of agency records about individuals, and the Privacy Act of 1974 (for the most part) applies to systems of records. 5 U.S.C. § 552a(b)(5).

[26] https://oma.od.nih.gov/forms/Privacy%20Documents/PAfiles/0012.htm. Whether a collection of records is a *system of records* under the Privacy Act of 1974 turns on a *factual* test about retrievability.

There are several ways that the Privacy Act of 1974 authorizes agencies to disclose personal information. The statute itself sets out twelve "conditions of disclosure" that define allowable disclosures for all Privacy Act systems of records.[27] One class of allowable disclosures is:

> to another agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency which maintains the record specifying the particular portion desired and the law enforcement activity for which the record is sought.[28]

Under this authority, an agency may share any Privacy Act record with any federal, state, or local law enforcement agency upon written request by the head of the agency. Disclosures are not mandatory, and an agency need not disclose a requested record if it chooses not to do soStill, the authority here is quite broad (any law enforcement activity "authorized by law"), tempered only by the procedural requirement that the request come from the head of the agency.

Another condition of disclosure of the Privacy Act allows an agency to disclose information pursuant to a *routine use*.[29] A routine use is a disclosure "compatible with the purpose for which [the record] was collected."[30] In modern privacy parlance, use generally refers to internal use by an organization that holds a record, and a disclosure means sharing a record with someone outside the organization. The Privacy Act is confusing in that a *routine use* is an external disclosure. An agency defines one or more routines uses for each system of records through a process similar to a rulemaking.[31]

The statutory standard for establishing a routine use is vague, and agencies often have expansive routine uses. Agencies frequently create routine uses to expand upon the disclosures for law enforcement purposes allowed by the statutory provision quoted above. The statutory provision just discussed requires a request from the head of the agency. Agencies have a routine use so they can initiate a disclosure without a request.

This type of routine use typically allows disclosures to federal and foreign law enforcement agencies if a record "indicates" any violation or potential violation of law. A similar routine use may allow disclosures to state and local law enforcement agencies. Here's an example.

> In the event that a system of records maintained by this agency or carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records

[27] 5 U.S.C. § 552a(b).
[28] 5 U.S.C. § 552a(b)(7).
[29] 5 U.S.C. § 552a(b)(3).
[30] 5 U.S.C. § 552a(a)(7).
[31] 5 U.S.C. § 552a(3)(11).

> in the system of records may be referred, as a routine use, to the appropriate agency, whether federal, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.[32]

Essentially, this routine use allows nearly standardless disclosure of any record to a civil or criminal law enforcement agency. Again, disclosures are discretionary and not mandatory. The authority, however, is quite broad. The routine use allows a disclosure in response to a request from an agency that does not meet the statutory condition of disclosure that requires a written request from the head of an agency.

This specific example of a law enforcement routine use quoted above comes from the agency-wide routine uses established by the Department of Health and Human Services. There are eight other HHS agency-wide routine uses covering other disclosures. Many agencies define agency-wide routine uses that apply to all agency systems of records for convenience. It is not entirely clear if the nine HHS routines uses applicable to more than one system of records actually apply to all agency records. Some legal details remain murky, and the specifics are not worth exploring here. Our best reading is that these apply to most HHS systems, including those maintained by NIH, which is a component of HHS. If NIH establishes a new system for PMI, it could define routine uses for that system, and it might find a way to avoid some of the agency-wide routine uses established by HHS.

The point is that the Privacy Act of 1974 gives agencies broad authority to establish a basis for disclosing records from a Privacy Act system of records. Most agencies use that authority to provide for expansive law enforcement disclosures. This could happen to any PMI system. It is possible that disclosures could be even broader. Remember that the HIPAA health privacy rule promulgated by HHS allows disclosures of any health record to any national security agency without any standards or process. The same policy might (or might not) apply to PMI records.

Further, Congress can, without changing the Privacy Act of 1974, require agencies to disclose records for additional purposes, making those purposes legislatively compatible with the purpose for which the records were originally collected. For example, in the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Congress directed each federal agency to disclose some agency records to a directory of new hires aimed at finding individuals with outstanding child support obligations. The Office of Management and Budget directed each agency to establish a new routine use for its payroll records.[33] Under exigent political circumstances,

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[32] Department of Health and Human Services, Privacy Act Regulation, 45 C.F.R. Part 5b, Appendix B, Routine Uses Applicable to More Than One System of Records Maintained by HHS, http://www.ecfr.gov/cgi-bin/text-idx?SID=8391cb1e1e023df7b045749be77396c9&mc=true&node=pt45.1.5b&rgn=div5#ap45.1.5b_113.b.

[33] See Sally Katzen, Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, *Privacy Act Responsibilities for Implementing the Personal Responsibility and Work Opportunity Reconciliation Act of 1996* (1997), https://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/katzen_prwora.pdf.

Congress could make any federal record available for new law enforcement, national security, or other activity.[34]

The Privacy Act of 1974's provisions on use and disclosure leave much to be desired. As documented above, the Act allows many types of disclosures to foreign, national, state, and local law enforcement agencies with few procedural prerequisites. We will not know what disclosures will be allowed for PMI until we see a system of records notice for a PMI system. Developing a system of records notice and obtaining approval can take months, and there is no draft notice yet available.

Finally, we observe that the Privacy Act of 1974 applies to federal agencies. If an agency discloses a Privacy Act record to another federal agency, the record may end up in a different system of records subject to an entirely different set of routine uses. However, if an agency discloses a Privacy Act record to anyone other than a federal agency, the rules of the Privacy Act do not follow the record, and the record may be subject to another or to no privacy law at all. This is similar to the way that HIPAA works.

Will Physician-Patient Privilege Survive if an Individual has Donated their Health Records and Biospecimens to the PMI Database?

Summary: A patient who consents to the disclosure of health records to PMI could lose the ability to claim a physician-patient privilege to shield documents and information from disclosure in judicial proceedings.

The law in many states recognizes a physician-patient testimonial privilege that serves to protect patient privacy by limiting what a physician's ability to testify about confidential communications between the patient and the physician. The privilege exists in most states, and it varies considerably in scope, application, and exemption across the states.[35] While the privilege has a limited value in many ways, it can be protective of privacy at times. The details of state law privileges are beyond the scope of this analysis.

What is important here is that the privilege can be lost under different circumstances. For example, a privilege may be lost if an otherwise confidential communication happened in the presence of a third person. The privilege can be lost by disclosure of privileged information to a third party. If a patient consents to the disclosure of his health record, the privilege may be

[34] Under HIPAA, stronger state laws take precedence, so if a state law prohibited a disclosure allowed by HIPAA, the disclosure would be illegal. This is not the case with the Privacy Act of 1974. If another law requires a disclosure, a federal agency just creates a new routine use.

[35] See generally, Robert Gellman, *Prescribing Privacy: The Uncertain Role of the Physician in the Protection of Patient Privacy*, 62 North Carolina Law Review 255 (1984).

waived. Once waived the privilege is lost. In the case of PMI, where a patient consents to a health record disclosure to PMI and, perhaps to an unknown and indefinite number of researchers in the future, there may be a strong argument that the patient waived any available privilege.

Because the physician-patient privilege is statutory, it could be reshaped by law to preserve the privilege. Whether a federal law could accomplish this type of change to state law rules of evidence is uncertain. It is also uncertain if the PMI initiative plans to address the privilege issue, either through notice to those who volunteer their records or through legislative proposals. The PMI Privacy and Trust Principles state that "[m]easures for protecting PMI data from disclosure in civil, criminal, administrative, legislative, or other proceedings should be explored." That suggestion does not appear to address clearly the privilege issue, an issue that affects records in their original location and not records in the hands of PMI. In any event, a promise to explore the issue at some indefinite time in the future has little value today.

Will the Legal Protections Afforded to Alcohol and Drug Abuse Patient Records Apply to the PMI Database?

Summary: Records disclosed to PMI from health care providers subject to federal substance abuse confidentiality rules would retain their confidentiality if disclosed to PMI.

A separate privacy regime applies to records maintained by most alcohol and drug abuse health care providers. The Substance Abuse and Mental Health Services Administration (SAMHSA) maintains the Confidentiality of Alcohol and Drug Abuse Patient Records regulations.[36] The rules are often referred to as *Part 2*.

The Part 2 rules have perhaps the strictest privacy rules of any American privacy law. The rationale is that patients in substance abuse programs may seek treatment for activities that violate drug abuse or other laws. Without some protections against law enforcement access to the records, patients might refuse to seek treatment. The Part 2 rules impose meaningful limits on disclosures to law enforcement by health care providers subject to Part 2. The details are beyond the scope of this analysis. However, it is unquestionable that the Part 2 protections against law enforcement disclosure are much better than those available under either HIPAA or the Privacy Act of 1974.

Part 2 has another interesting provision absent from the other laws already discussed. The Part 2 rules generally follow the record when disclosed by a substance abuse program. This means that the sensitive information in the record remains protected despite its disclosure. This may be the

[36] 42 C.F.R. Part 2. SAMHSA is in the process of revising the rules. See 81 Federal Register 6988 (February 9, 2016), https://www.gpo.gov/fdsys/pkg/FR-2016-02-09/pdf/2016-01841.pdf.

only American privacy law where privacy rules follow the records. Remarkably, this policy applies even when a patient consents to the disclosure of the patient's record.[37]

If a patient agrees to the disclosure of a HIPAA record to PMI, the HIPAA rules do not accompany the disclosure unless the record goes to a covered entity subject to HIPAA. If a patient agrees to the disclosure of a Privacy Act of 1974 record, the privacy rules of the Act may apply (but in different ways) if the recipient is a federal agency, but the privacy rules do not apply if the recipient is not a federal agency. However, if a patient consents to the disclosure to the PMI of substance abuse records subject to Part 2, the Part 2 restrictions follow the record. Needless to say, this presents significant administrative challenges when a recipient accepts Part 2 records because the applicable confidentiality regime is different and stricter than any other potentially applicable law.

Do Certificates of Confidentiality Provide Enough Protection for PMI Data and Biospecimen Donors?

Summary: Certificates of confidentiality provide researchers a defense against compelled disclosures. While there are some uncertainties about the value of certificates, PMI data covered by a certificate would likely have some protection against subpoenas and the like.

A certificate of confidentiality authorized by some federal statutes provides some protection against compelled disclosure of records held by researchers. The certificate authorizes a researcher to resist compulsory legal demands (such as a court order or subpoena) for identifiable research information about individuals. The Public Health Service Act establishes one of the broadest certificate programs.[38] The law allows the Secretary of HHS to issue a certificate of

[37] 42 C.F.R. § 2.32. The notice that accompanies a disclosed record must include this statement: "This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient."

[38] 42 U.S.C. § 241(d) ("The Secretary [of Health and Human Services] may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."). These certificates are available on project-by-project basis from NIH, the Food and Drug Administration, the Substance Abuse and Mental Health Services Administration, the Centers for Disease Control, the Indian Health Service, and the Health Resources and Services Administration. For more information on certificates and the process for obtaining them, see NIH's Certificates of Confidentiality Kiosk at http://grants.nih.gov/grants/policy/coc/index.htm.

confidentiality not only to federally-supported research, but to other research as well. The Secretary requires that a research project seeking a certification obtain institutional review board approval of the research protocol.

PMI records used by researchers – and the PMI records themselves held by a PMI manager – could well qualify a certificate of confidentiality. NIH operates the certificate program, and there seems little doubt that it could lawfully grant certificates for many PMI data activities. If so, then certificates of confidentiality would provide a degree of protection against compelled disclosure.

The actual value of a certificate is questionable, however. First, it protects against *compelled* disclosures, but it say nothing about volunteered disclosures. A researcher faced with a long, expensive, and unfunded battle to protect records could voluntarily disclose the records and avoid the battle altogether. Second, and similarly, a certificate holder is not required to resist demands for records. The law provides that certificate holders are *authorized* to resist demands, but they are not compelled to do so. Third, the actual value of the certificate of confidentiality is somewhat in doubt. The uncertainty is wonderfully summarized in a recent journal article that provides examples of cases where a court meaningfully upheld a certificate or essentially disregarded it.[39] The lesson is that you do not know the value of a certificate until a judge issues a ruling in a particular case before a court. Fourth, certificates are only available for research activities. If PMI allows or tolerates non-research uses of PMI data, a certificate may not be available or may offer no protection.

The shortcomings of laws establishing certificate of confidentiality programs are beyond the scope of this analysis. However, it is probably fair to assume that NIH would take steps to place most or all PMI activities under certificate protection. NIH could also require those using PMI data to sign a data use agreement compelling users to resist compelled disclosures and to refuse to make voluntary disclosures (at least those without data subject consent). If so, then research activities that receive certificates would be in a better position to protect the records against compelled disclosure. Without certificates, however, PMI records could be vulnerable just like any other record to compelled disclosure for civil and criminal purposes. Still, the value of a certificate remains uncertain and could vary from case to case as happened in the past.

Issues Relating to Consensual Disclosures

Summary: Third parties may seek access to PMI health records with the consent of the data subjects. PMI rules governing third party access are unknown.

Other statutes that provide for certificates of confidentiality or the equivalent include: 42 U.S.C. § 242m(d); 42 U.S.C. § 299c-3(c); 42 U.S.C. § 290aa(n); 42 U.S.C. § 3789g(a); 42 U.S.C. § 10604(d); and 44 U.S.C. § 3501 note. Some state laws may also provide comparable protections for some research activities.

[39] Leslie E. Wolf, Mayank J. Patel, Brett A. Williams, Jeffrey L. Austin, Lauren A. Dame, Certificates of Confidentiality: Protecting Human Subject Research Data in Law and Practice, 14 Minnesota Journal of Law, Science, and Technology 11 (2013). http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2217833.

Under some circumstances, individuals give consent for the sharing of their health records with third parties. With an appropriately signed consent form, health record holders, including HIPAA covered entities, can share records with those third parties.[40] PMI records may be attractive to some users and more preferable than other health records. Much will depend on the scope and currency of the records. For example, someone may seek PMI records rather than other records about a patient if PMI collects in one place records from diverse sources and multiple health care providers. PMI may also have records that are unavailable from the original source in some cases.

For example, an individual seeking a security clearance in order to have access to classified information must sign a broad consent form allowing any source of information about the individual to disclose the information with a federal investigator. In addition, the applicant for a security clearance signs a specific authorization consistent with HIPAA.[41] The consent granted under Standard Form 86 (Questionnaire for National Security Positions) appears broad enough to cover records held by PMI.

For example, an individual applying for life insurance is typically signs a broad consent form that allows disclosure of personal information from both HIPAA and non-HIPAA sources. If the consent form currently in use is not broad enough to cover PMI, it could be easily amended. The advantage to insurers might be a faster response and obtaining in one place records that originated from more than one source.

Whether PMI would respond to requests from third parties armed with data subject consents is unknown. There are good arguments for and against allowing consensual disclosures to third parties. Data subject access is a basic privacy practice and part of the PMI Privacy and Trust Principles. The details of how access would be provided remain unknown. If PMI followed the policy in the HIPAA privacy rule, it might well allow third parties to exercise the access right that an individual has with the consent of the individual.[42] The Privacy Act of 1974 provides for data subject access, but it is not clear if that access right can be exercised by a third party with consent. The Act provides that an individual inspecting personal records can bring a third party to accompany him.[43] We do not know which, if any, existing model the PMI would follow.

The creation of any new compilation of information may bring with it new and possibly unexpected requests and demands for access to the information. Remote data users may find value in an information resource and, when armed with individual consent, may seek records that they might not be able to obtain otherwise. Consider, for example, if a direct marketer or database vendor, found a way to induce an individual to share access to that individual's health record. Without a clearly stated set of rules and policies, the availability of records in PMI will remain uncertain and patient privacy could be threatened.

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[40] HIPAA allows disclosures with an authorization from the patient. 45 C.F.R. § 164.508. Under a separate procedure, a patient's may designate another person to have a copy of his record under the provision that allows a patient access to his own record, and a covered entity must disclose the record. 45 C.F.R. §528(c)(3)(ii). The Privacy Act of 1974 allows disclosures pursuant to a written request from the data subject. 5 U.S.C. 552a(b).

[41] Standard Form 86 (2010) at page 21, http://www.dea.gov/careers/agent/sf86.pdf.

[42] 45 C.F.R. §528(c)(3)(ii).

[43] 5 U.S.C. § 552a(d)(1).

Recommendations

1. The PMI needs to detail its structure and organization with clarity so that the privacy protections or lack of privacy protections for its records can be assessed. The public needs to know what institutions will maintain information in the PMI and where they are located. The PMI must explain how privacy laws, if any, will apply to it. The privacy and security standards issued so far do not answer the questions about what legal protections will apply.

2. The PMI should not begin soliciting information or biospecimens from or about individuals until it clearly describes the applicable privacy protections. The description should include potential uses and disclosures of PMI information for law enforcement and national security purposes. The description of applicable privacy rules should cover health records, administrative records, and any real-time monitoring from mobile or other devices. Volunteers should be told expressly if HIPAA does not apply to the PMI.

3. The E-Government Act of 2002 requires agencies to conduct a Privacy Impact Assessment before they develop or procure information technology systems or projects that collect, maintain or disseminate information in identifiable form from or about members of the public.[44] We have not seen a PIA for the PMI. There is an immediate need for a PIA that includes an opportunity for public comment and debate.

4. If the Privacy Act of 1974 applies to PMI or any significant part of it, then the National Institutes of Health should publish a system of records notice and allow adequate time for public comment

5. If the Privacy Act of 1974 does not apply to PMI, then it is possible that no health privacy or other privacy law will apply to most of the data or biospecimens. As a result, the data could be vulnerable to a host of unrelated public and private demands and activities. If so, then PMI may need its own privacy law in place before it starts.

[44] See Office of Management and Budget, Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002 (2003)(M-03-22), https://www.whitehouse.gov/omb/memoranda_m03-22/.

Conclusion

Creating a national database of health and genetic information for medical research is a laudable goal. However, creating a large new health information database without clear privacy laws and rules that protect individuals' medical data and gives them enforceable rights has the potential for negative consequences for individual donors. Sloppy use and disclosure of PMI records could also damage the PMI effort itself. Privacy principles are fine, but they are not the law. Privacy principles do not provide volunteers with firm and enforceable legal protections.

Privacy is a complex, multi-layered issue and encompasses many aspects of choice, autonomy, and fair information practices. PMI volunteers will be much more likely to provide their health information and biospecimens in support of the long-term goals of medical research if they have enforceable legal privacy protections.

About this Report and Credits

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Background information and research for this report was collected from extensive public, official sources available regarding the PMI.

Appendix A: Timeline of the Precision Medicine Initiative

Jan. 20, 2015: President Obama announced the Precision Medicine Initiative in his State of the Union Address.

Jan. 30, 2015: White House event with patients, advocates, scientists, and industry leaders. President Obama shared his vision for the Initiative to enhance innovation in biomedical research with the ultimate goal of moving the U.S. into an era where medical treatment can be tailored to each patient.

Feb. 11-12, 2015: National Institutes of Health conducts the first workshop on PMI.

March 30, 2015: ACD PMI working group established.

April 28-29, 2015: Public Workshop on Unique Scientific Opportunities for the National Research Cohort Workshop (NIH).

May 5, 2015: Senate hearing, Continuing America's Leadership: Realizing the Promise of Precision Medicine for Patients.

May 28-29, 2015: Digital Health Data in a Million-Person PMI Cohort Workshop (Vanderbilt University).

July 1-2 2015: Participant Engagement and Health Equity Workshop (NIH).

July 27-28, 2015: Mobile Technologies in a Precision Medicine Initiative Cohort (Intel).

Sept. 17, 2015: ACD PMI Working Group Report.

Sept. 25, 2015: NIH Stakeholder Briefing on the PMI Working Group Final Report.

Dec. 17, 2015: PMI Cohort Program Advisory Panel Meeting.

Jan. 14, 2016: Pre-Application Technical Assistance Webinar for the Precision Medicine Initiative (PMI) Cohort Program Requests for Applications.

Jan. 15, 2016: PMI Cohort Program Advisory Panel Meeting.

Feb. 2016: Vanderbilt University Medical Center is announced as first PMI funding recipient.

Summer 2016: (planned) The NIH announces it will award cooperative agreements for the full implementation phase of the PMI. This includes establishing a coordinating center to oversee direct volunteer recruitment, healthcare provider organizations to enroll more participants, and a Biobank capable of storing and managing blood, urine and saliva samples for analysis. (http://news.vanderbilt.edu/2016/02/vumc-to-lead-pilot-program-for-precision-medicine-initiative-cohort-program/).

Dec. 2016: (planned) ~79,000 engaged participants fully consented and enrolled in the Cohort and collection of biospecimens from at least 25,000 participants.

Appendix B: Donated Information from Individuals and Patients

Participants in the PMI will donate a variety of information, including blood and other biospecimen samples, along with health records and other data, see Illustration 1. Discussions are ongoing about additional data collections that include geolocation, cell phone data, social networking data, and potentially even over-the-counter medication purchases. See Illustration 2.

1. Initial core data set to be collected from volunteers

Initial Core Data Set

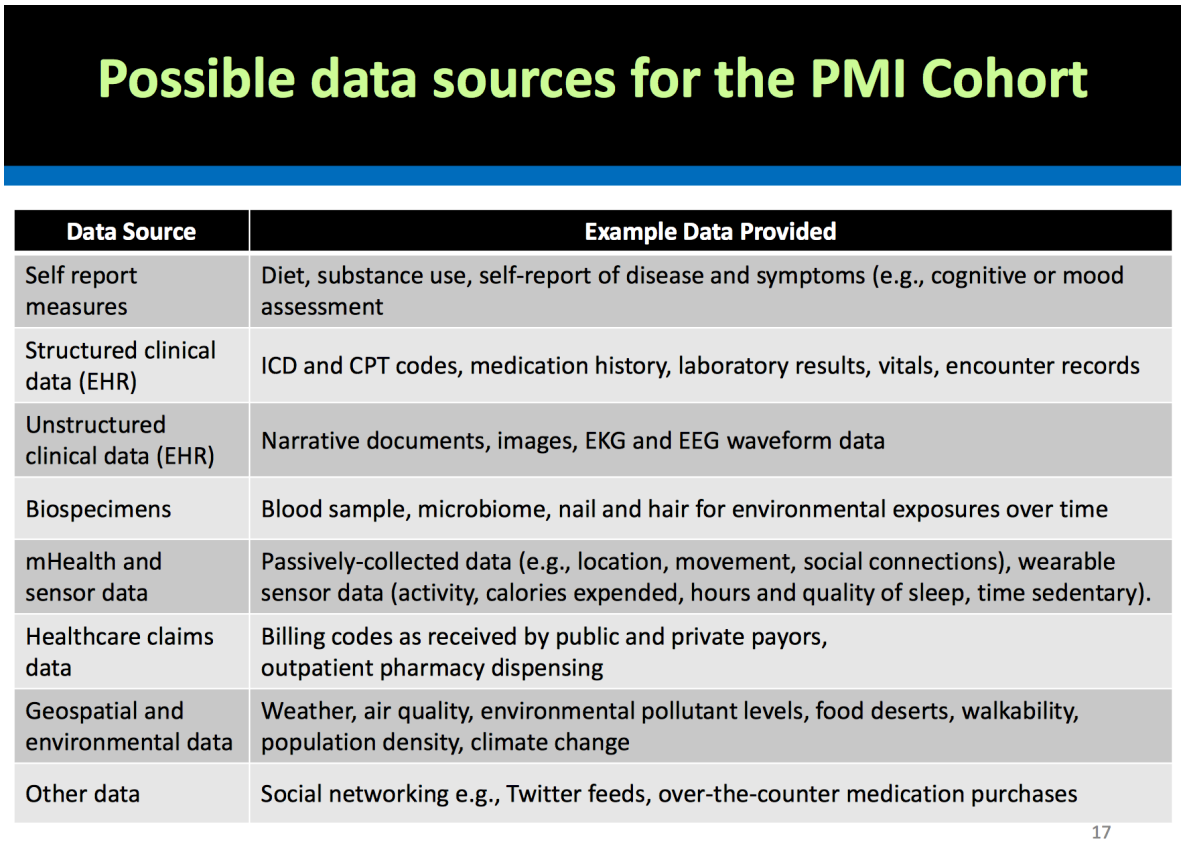
- Centrally collected and stored in a Coordinating Center
- Align with other data sets when possible
- Leverage existing data standards and common data models when possible

Data Source	Data Provided
Self report measures	Diet, substance use, self-report of disease and symptoms (e.g., cognitive or mood assessment)
Baseline health exam	Vitals (e.g., pulse, blood pressure, height, weight), medical history, physical exam
Structured clinical data (EHR)	ICD and CPT codes, medication history, select laboratory results, vitals, encounter records
Biospecimens	Blood sample
mHealth data	Passively-collected data (e.g., location, movement, social connections) from smartphones, wearable sensor data (activity, hours and quality of sleep, time sedentary).

Illustration 1: Initial Core Data Sets from Data Donors to the PMI

Source: https://www.nih.gov/sites/default/files/research-training/initiatives/pmi/pmi-advisorypanel-slides-20160115.pdf

2. Potential data to be collected from or about volunteers, and data sources



Possible data sources for the PMI Cohort

Data Source	Example Data Provided
Self report measures	Diet, substance use, self-report of disease and symptoms (e.g., cognitive or mood assessment
Structured clinical data (EHR)	ICD and CPT codes, medication history, laboratory results, vitals, encounter records
Unstructured clinical data (EHR)	Narrative documents, images, EKG and EEG waveform data
Biospecimens	Blood sample, microbiome, nail and hair for environmental exposures over time
mHealth and sensor data	Passively-collected data (e.g., location, movement, social connections), wearable sensor data (activity, calories expended, hours and quality of sleep, time sedentary).
Healthcare claims data	Billing codes as received by public and private payors, outpatient pharmacy dispensing
Geospatial and environmental data	Weather, air quality, environmental pollutant levels, food deserts, walkability, population density, climate change
Other data	Social networking e.g., Twitter feeds, over-the-counter medication purchases

17

Illustration 2: Potential donor data sets to contribute to PMI data.

Source: https://www.nih.gov/sites/default/files/research-training/initiatives/pmi/pmi-advisorypanel-slides-20160115.pdf

Appendix C: Governance Chart for the PMI

This governance chart was published at the most recent meeting of the PMI. (Illustration 3.) The governance of the PMI may undergo further iterative changes.

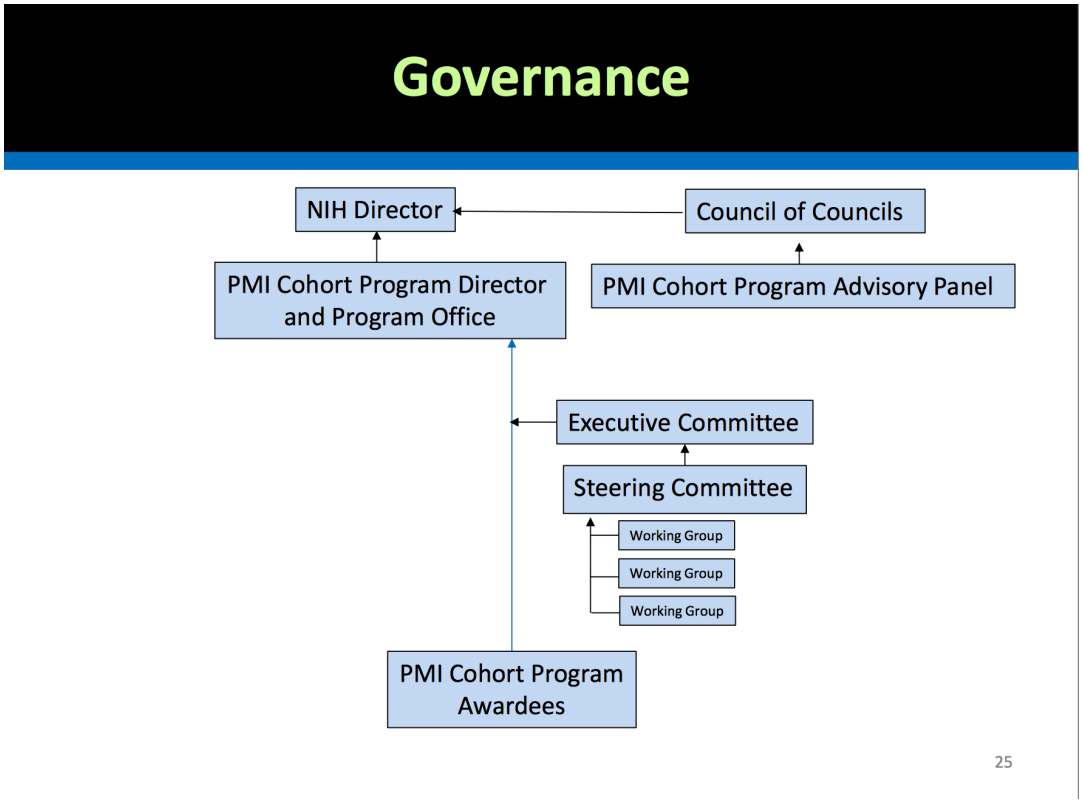


Illustration 3: Governance chart of the PMI.

Source: https://www.nih.gov/sites/default/files/research-training/initiatives/pmi/pmi-advisorypanel-slides-20160115.pdf