



August 3, 2015

Submitted electronically

Dr. Francis S. Collins, M.D.  
Director, National Institutes of Health  
9000 Rockville Pike  
Bethesda, Maryland 20892

RE: PRECISION MEDICINE INITIATIVE: PROPOSED PRIVACY AND TRUST PRINCIPLES

Dear Dr. Collins:

The National Partnership for Women & Families appreciates this opportunity to comment on the proposed Privacy and Trust Principles for the White House's Precision Medicine Initiative, and commends the White House and the interagency working group for the careful work to draft them. The National Partnership is a leading non-profit, non-partisan organization working to promote access to high-quality health care, fairness in the workplace, and programs and policies that help women and men meet the demands of work and family. The National Partnership leads the Consumer Partnership for eHealth (CPeH), a coalition of more than 50 consumer, patient and labor organizations working since 2005 to advance electronic health information technology and exchange (health IT) in ways that measurably improve the lives of individuals and families.

The Precision Medicine Initiative holds great promise to improve the health of the nation through the promotion of innovative research and personalized approaches to prevention and treatment. We agree wholeheartedly with the President's goal for the Precision Medicine Initiative (PMI) outlined in this year's State of the Union address to give all Americans access to the personalized information that we need to keep ourselves and our families healthier. Our research shows that easy, useful electronic access to one's health information is a catalyst for engaging patients and families in their care. Patients who use online access more frequently report a substantial increase in positive impact on knowledge of their health and desire to do something to improve their health.<sup>1</sup> Recent advances in health IT, including electronic health record (EHR) adoption and efforts to expand patients' electronic access to their own health data, are foundational to the success of this initiative. With our recommendations below, we think that the proposed Privacy and Trust Principles provide excellent support for participants' active engagement in the research cohort and moreover in their health and care.

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<sup>1</sup> National Partnership for Women & Families. (2014, December). *Engaging Patients and Families: How Consumers Value and Use Health IT*, from <http://www.nationalpartnership.org/research-library/health-care/HIT/engaging-patients-and-families.pdf>, p. 29.

## *Fundamental Assumptions about the PMI Cohort*

We appreciate the Administration’s recognition that privacy and trust are integral to a successful partnership between participants and members of the research community. In order for the initiative to succeed, participants must value and trust the wide-scale collection and use of their health data (including clinical, genetic, environmental and lifestyle information). The National Partnership’s survey data offer insight that may apply to the initiative: The more patients experience the benefits of EHRs – specifically online access to their own health information – the more they trust that their providers using EHRs are protecting patients’ privacy.<sup>2</sup> Our survey also found that almost 90 percent of patients whose doctors use EHRs report that it is important for them to know how their health information is collected and used, but only 55 percent stated that their doctors and staff did a good job of explaining how their information is used.<sup>3</sup> Thus, enhancing participants’ access to their own health information, and educating them about the collection and use of this data, will be foundational to securing and bolstering participant trust, and ultimately the success of the PMI.

This theme of partnership with participants is readily apparent in the Initiative’s Fundamental Assumptions about the PMI Cohort, particularly in the affirmation that participants should play an integral role in governance (#4). The National Partnership strongly supports requiring participant involvement in any coordinated governance process. Participants and their families bring unique perspectives that can help to advance research in precision medicine. Including participants, family members and consumer advocates on governing boards and bodies will ensure that these unique perspectives are considered in the development of policies and procedures. Bringing such insights to light, however, requires engaging patient and family representatives in meaningful ways.<sup>4</sup>

Moreover, we appreciate the recognition that increasing participants’ ability to access their own medical information is central to success (#6). As we have mentioned, we believe that individuals’ access to their own health information is a game-changer for many spheres of health and care, including research. However, we encourage the PMI to consider that success is only truly facilitated by both individuals’ access to and *use of* health information, and thus propose this addition to the assumption. In our survey, patients want more than the mere ability to view their health information; they want to use it to improve their health, to communicate with their doctors, and to share relevant health information with family members, among other things—all of which promote greater engagement in their health.<sup>5</sup>

Finally, by promoting participant contribution of data, including data on social determinants of health, this fundamental assumption (#5) positions participants as true partners in the research process and allows for the collection of data critical to the identification of health needs and successful treatments.

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<sup>2</sup> *Id.*, p. 39.

<sup>3</sup> *Id.*, p. 40.

<sup>4</sup> Carman, K., Dardess, P., Maurer, M., Sofaer, S., Adams, K., Bechtel, C., & Sweeney, J. (2013). Patient and Family Engagement: A Framework for Understanding the Elements and Developing Interventions and Policies. *Health Affairs*, 32(2): 223-23.

<sup>5</sup> National Partnership for Women & Families. (2014, December). *Engaging Patients and Families: How Consumers Value and Use Health IT*, from <http://www.nationalpartnership.org/research-library/health-care/HIT/engaging-patients-and-families.pdf>, pp. 23-31.

## *Governance*

Once again, we greatly appreciate the intention to include participants as integral members of a governance structure and throughout all levels of program oversight, design, and implementation (#2).

## *Reciprocity*

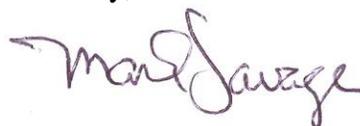
While we strongly support the aim of these principles – providing participants access to medical information and educational resources – we propose recategorizing the principles as *Partnership* (or *Supporting Partnerships with Participants*).” The current *Reciprocity* label seems to imply that resources are provided to participants *after* their involvement in the PMI cohort, yet participant access to data and educational resources are critical to successful participation, and should be promoted throughout continued interaction to foster partnership. For instance, participants would need access to their medical information during their participation in order to contribute this information to the PMI (#1). We support providing participants with relevant findings following the conclusion of research studies, but consider this type of reciprocity insufficient for promoting knowledge of health and engagement.

## *Data Quality and Integrity*

We greatly appreciate the principle recognizing that participants should be able to easily report inaccuracies in their information maintained by the PMI (#3). Increased access by individuals to their own health information will surely increase the number of errors identified by patients, thereby underscoring the need for this capability. Providing individuals with an ability to correct information helps to improve the accuracy, reliability and quality of data, and underscores that patients are important sources of clinical information. Submitting requests for amendments is enabled by the use of health IT, specifically patient portals for access to health information or secure messaging features, and we encourage the PMI to consider employing these means to facilitate this important component of data quality efforts.

Thank you again for the opportunity to submit comments on the Precision Medicine Initiative’s Proposed Privacy and Trust Principles. We stand ready to be a resource to the Administration and the Initiative in this critical effort to give all Americans access to the personalized health information and medicine that we need to improve the health of ourselves and our families. If you have any thoughts or questions about these comments, please contact Mark Savage at (202) 986-2600 or [MSavage@nationalpartnership.org](mailto:MSavage@nationalpartnership.org).

Sincerely,



Mark Savage  
Director, Health Information Technology Policy  
and Programs

cc: Kathy Hudson, Ph.D., Deputy Director of Science, Outreach, and Policy,  
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