

January 10, 2020

Andrea Jackson-Dipina, Dr.PH
Director of the Division of Scientific Data Sharing Policy
Office of Science Policy
National Institute of Health
Department of Health and Human Services
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892

RE: Comments of the Connected Health Initiative on *Request for Public Comments on a DRAFT NIH Policy for Data Management and Sharing and Supplemental DRAFT Guidance* (84 FR 60398)

Dear Dr. Jackson-Dipina:

The Connected Health Initiative (CHI) appreciates the opportunity to provide input on the National Institutes of Health's (NIH) Draft Policy for Data Management and Sharing and Supplemental Draft Guidance, intended to promote effective and efficient data management and sharing.¹ Therefore, this draft policy and supplemental guidance will further NIH's commitment to making the results and accomplishments of the research it funds and conducts available to the public.

CHI represents a broad consensus of stakeholders across the healthcare and technology sectors whose mission is to support the responsible and secure use of connected health innovations throughout the continuum of care to improve patients' and consumers' experience and health outcomes. We advocate before the Department of Health and Human Services (HHS) on realizing the benefits of an information and communications technology-enabled American healthcare system. CHI is committed to advancing an interoperable healthcare system that enables the bidirectional flow of necessary health data between provider and patient, as well as between other important stakeholders who have a role in improving care coordination and decision-making.

The efficacy of precision medicine, population health, clinical decision support—and artificial/augmented intelligence (AI)- driven tools in particular—is dependent in large part on the availability of massive data sets. The free flow of information and interoperability are therefore important and potentially life-saving for patients.

¹ [84 Fed. Reg. 60398 \(Nov. 27, 2019\)](#).

NIH's proposed policy comes at an important time. There is no disputing that interoperability and patient access to health information prevent timely and informed care coordination and decision-making. Further, electronic health information and educational resources are critical tools that empower and engage patients in their own care regimens. CHI strongly believes that a truly interoperable eCare system includes patient engagement facilitated by store-and-forward technologies (ranging from connected medical devices to general wellness products) with open application programming interfaces (APIs) that allow the safe and secure introduction of patient-generated health data (PGHD) into electronic health records (EHRs). Data stored in standardized and structured formats with interoperability facilitated by APIs provides analytics as well as near real-time alerting capabilities. The use of platforms for data streams from multiple and diverse sources will improve the healthcare sector, helping to eliminate information silos, data blocking, and deficient patient engagement. Interoperability must not only happen between providers, but also between remote patient monitoring (RPM) products, medical devices, and EHRs. NIH's approach to data management and sharing are important for those stakeholders directly engaged with NIH, as well as to the wider healthcare community through the precedent NIH sets.

Based on the above, we provide the following viewpoints and recommendations on NIH's draft policy:

- CHI is generally supportive of NIH's efforts to update and improve its approach to data management and sharing. Specifically, we support NIH making scientific data publicly available at no (or nominal) cost in as timely a manner as possible. However, we believe that NIH's approach, as proposed, may not align with information sharing norms in the public and private sector.
- A logical, objective approach is necessary to reduce confusion, and NIH should align its data management and sharing policy with the Office of the National Coordinator for Health IT's (ONC's) information blocking to the extent possible. While this rule is currently approaching finalization, it will represent the baseline for information sharing moving forward, and NIH should align its data management and sharing policies with these rules to the maximum extent possible to provide continuity across the healthcare ecosystem. For example, CHI recommends use of the Fast Healthcare Interoperable Resources (FHIR) standard (Release 4) as well as HL7 U.S. Core FHIR Implementation Guides (or in the alternative that NIH permit the use of such widely-accepted standardized approaches to information sharing).
- CHI generally supports preserving and sharing data through established repositories, but also encourages enabling APIs to facilitate streamlined data flows. However, NIH's data management and sharing policy completely omits discussion of APIs and how NIH contemplates APIs playing a role in its sharing of data. We believe this is an oversight that NIH needs to address before its policy is finalized. We strongly encourage NIH to facilitate the use of two-way APIs for management and sharing of data.

- CHI generally supports NIH’s efforts to respect the autonomy and privacy of research participants and protection of confidential data. We again urge NIH to align its policies with the efforts of other key health sector agencies (e.g., ONC, HHS’ Office of the Inspector General, etc.). CHI proposes that health data transparency can be advanced through the use of three “yes/no” attestations that NIH can share answers with for research participants to ensure they make informed decisions about how the technology being used handles privacy. Such questions should be to answer whether (1) the technology conforms to Xcertia’s Privacy Guidelines;² (2) the technology developer attests to the Federal Trade Commission’s *Mobile Health App Developers: FTC Best Practices* and the CARIN Alliance Code of Conduct;³ and (3) the technology developer attests to adopting and implementing ONC’s Model Privacy Notice.⁴ NIH should publicize these attestations to promote research participants’ informed decision making and transparency.

CHI appreciates the opportunity to submit its comments to NIH. We look forward to assisting NIH in modernizing and improving its data management and strategy.

Sincerely,



Brian Scarpelli
Senior Global Policy Counsel

Alexandra McLeod
Policy Counsel

Connected Health Initiative
1401 K St NW (Ste 501)
Washington, DC 20005

² XCERTIA MHEALTH APP GUIDELINES, <https://xcertia.org/wp-content/uploads/2019/08/xcertia-guidelines-2019-final.pdf> (issued on August 12, 2019).

³ *Mobile Health App Developers: FTC Best Practices*, F.T.C., <https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-app-developers-ftc-best-practices> (issued April 2016).

⁴ *Model Privacy Notice*, ONC, <https://www.healthit.gov/topic/privacy-security-and-hipaa/model-privacy-notice-mpn>.