



November 20, 2013

Genomic Data Sharing Policy Team  
Office of Science Policy  
National Institutes of Health  
6705 Rockledge Drive Suite 750  
Bethesda, MD 20892

Re: Draft NIH Genomic Data Sharing Policy Request for Public Comments

Dear Genomic Data Sharing Policy Team:

On behalf of the American Health Information Management Association (AHIMA), I am pleased to provide comments on the “Draft NIH Genomic Data Sharing (GDS) Policy” as drafted and published by the Office of Science Policy of the National Institutes of Health (NIH).

AHIMA is the national non-profit association of health information management (HIM) professionals with component state associations in all 50 states, the District of Columbia and Puerto Rico. There are more than 71,000 members nationally who are dedicated to effective and efficient health information management. HIM professionals work for more than 40 different settings including hospitals, physician offices, long term care organizations, clinics, health information technology vendors and developers, consulting firms, life science companies, and government and education systems. AHIMA’s members can be found in numerous and diverse roles with a wide range of responsibilities. Individual members are hospital administrators; deans of universities; lawyers; privacy and compliance officers; data stewards; government officials; coders and data analysts; and consultants and industry professionals.

Our members typically manage electronic health record (EHR) systems and oversee increasingly complex and vital health information management principles and processes in various care delivery settings. AHIMA and its members help assure quality, cost effective, and efficient health and healthcare through data and information governance and stewardship. As the data and information custodians of healthcare organizations’ health records (whether paper or electronic) and leaders in the effective management of health information, ensuring the privacy, security, and confidentiality of personal health information has been a fundamental principle for the health information management (HIM) profession throughout its 85-year history. Today, HIM professionals continue to face the challenge of maintaining the privacy and security of patient information, an effort that grows in complexity as information becomes more and more distributed in electronic systems. The challenge of this responsibility has also increased due to the constantly changing legislative and regulatory environment. Ongoing efforts to share and exchange health data and information continue to present policy, operational, technological and ethical issues.

In providing input, we will address selected topics identified in the request for comment, as well as provide some general comments regarding the ongoing need to ensure the appropriate use of health data and information for research, based on AHIMA’s previous and ongoing work in this area.<sup>1 2</sup>

### **NIH Draft GDS Policy**

AHIMA acknowledges that the draft GDS Policy supports the NIH’s mission to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.<sup>3</sup>

### ***Data Submission Expectations and Timeline***

AHIMA agrees that human data that are submitted to the NIH-designated data repositories should be de-identified according to the standards set forth in the HHS Regulations for the Protections of Human Subjects and the HIPAA Privacy Rule. We are generally supportive of the proposal that the de-identified data should be assigned a random, unique code and the key to that code be held by the submitting institution. However, AHIMA further recommends that the GDS specifically delineate what happens to the human data that is received that is not de-identified as required. Processes to address such instances should include quarantining the identifiable data, returning it to the institution, and prohibiting its use unless or until it is de-identified as required.

AHIMA agrees that a Certificate of Confidentiality as defined by NIH<sup>4</sup> could serve as an additional safeguard to prevent compelled disclosure of any personally identifiable information that it holds in NIH-designated data repositories.

### ***Data Repositories***

Although AHIMA agrees that investigators who elect to submit data to a non-NIH-designated data repository should confirm that the appropriate data security, confidentiality, and privacy measures are in place, we recommend that NIH define the process for this confirmation. In addition, AHIMA believes that the GDS should specifically articulate and include the appropriate requirements for information governance, data security, confidentiality, and privacy (<http://www.ahima.org/topics/infogovernance>).

### ***Informed Consent***

AHIMA supports the specificity required for the informed consent including that it states that “a participant’s genomic and phenotypic data may be shared broadly for future research purposes and also explain whether the data will be shared through open or controlled access.” AHIMA recommends that the GDS policy should state that the NIH “...**requires** that participants will have provided explicit consent...” rather than “...**expects** that participants will have provided explicit consent...” Additionally, rather than an “expectation” for future research use, it should be a “requirement” that “...the informed consent for future research use and broad data sharing will have been obtained even if the cell lines or clinical specimens are de-identified.” In this regard, informed consent is a tool to provide the subject with knowledge of how their information will be used and how their privacy will be protected. Therefore, the privacy protection provided by the informed consent and the NIH should be a requirement, not an expectation.

Further, AHIMA believes that informed consent should include:

1. Notification that even despite due diligence and strong privacy protections that take steps to de-identify information, genetic information can sometimes be re-identified; and,
2. That individuals donating DNA or participating in research should be aware that privacy implications may exist that extend beyond themselves to family members or those who share their genome, including parents, siblings, children, adoptees, birth parents, sperm donors, and others.

When one donates DNA, he/she is also donating information about others. The donors need and should be made aware of this in the informed consent.

AHIMA agrees that data use limitations should be specified in the Institutional Certification submitted to the NIH prior to the research award. It should further specify the requirements regarding any permissible/allowable data use.

### ***Institutional Certification***

AHIMA recommends adding the following bullet point:

- The data submission and ultimate use is in accordance with the ethical use of health information.

According to AHIMA's Code of Ethics,<sup>5</sup> the ethical obligations of the health information management (HIM) professional include the safeguarding of privacy and security of health information; disclosure of health information; development, use, and maintenance of health information systems and health information; and ensuring the accessibility and integrity of health information.

AHIMA believes that healthcare consumers are increasingly concerned about security and the potential loss of privacy and the inability to control how their personal health information is used and disclosed. Core issues include what data should be collected, how the data should be handled, who should have access to the data, under what conditions the data should be disclosed, how the data are retained and if/when data are no longer needed, and how data are disposed of in a confidential manner. Harmonization with other federal as well as applicable state regulations is also critical.

Ethical obligations are central to the professional's responsibility, regardless of the employment site or the method of collection, storage, and security of health information. In addition, sensitive information (e.g., genetic, adoption, drug, alcohol, sexual, health, and behavioral information) requires special attention to prevent misuse. In the increasing complex world health services and biomedical research, interactions with consumers, requires expertise in the protection of the information.

### ***Exceptions to Data Submission Expectations***

As in the Informed Consent section, we recommend elevating "expected" to "required" in this section. Additionally, as in the Institutional Certification section, we recommend adding the following bullet:

- Submitting and using data in accordance with their ethical use.

### ***Acknowledgment Responsibilities***

As in earlier sections, we recommend elevating "expected" to "required."

### ***Conclusion***

AHIMA appreciates and supports the use of health information for research and scientific value and agrees that data use must be conducted done in accordance with all applicable laws, regulations, institutional polices and *ethical requirements*.

Thank you for providing the opportunity to comment and we look forward to working with you on the further development of the Draft GDS Data Sharing Policy. If we can provide any further information, or if there are any questions regarding our feedback, please feel free to contact me or Meryl Bloomrosen, Vice President, Thought Leadership, Practice Excellence, and Public Policy at [Meryl.bloomrosen@ahima.org](mailto:Meryl.bloomrosen@ahima.org). Please let us know if we can be of further assistance to you in your efforts.

Sincerely,



Lynne Thomas Gordon, MBA, RHIA, CAE, FACHE, FAHIMA  
Chief Executive Officer

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<sup>1</sup> <http://perspectives.ahima.org/critical-issues-in-bioinformatics-and-computing/#.Uo0qapWA3IU>

<sup>2</sup> <http://perspectives.ahima.org/flexible-approaches-for-teaching-computational-genomics-in-a-health-information-management-program/#.Uo0q5JWA3IU>

<sup>3</sup> Draft NIH Genomic Data Sharing Policy Request for Public Comment. September 20, 2013.

<sup>4</sup> <http://grants.nih.gov/grants/policy/coc/>

<sup>5</sup> [AHIMA Code of Ethics](#). Revised and Adopted 2011.