MOSES & SINGER LLP

Client Alert

February 2013

Genetic Privacy Concerns May Trigger Informed Consent Changes

As we reported in a previous Client Alert, there is increasing concern and awareness regarding the protection of research subjects' genomic and genetic information. Most recently, a highly-publicized study in Science magazine reported that it is possible to identify research participants from de-identified genetic data. The study highlights the privacy risks and vulnerabilities of genetic and genomics data and demonstrates the need for organizations involved in research to have clear guidelines and practices regarding the informed consent of research subjects participating in genetic or genomic research.

Sharing research data is critical to the advancement of science. The dissemination of data, including genetic information and genomic data, to researchers via the internet has become the standard for many collaborative research models.

A group of researchers from Massachusetts Institute of Technology recently published a study in Science magazine that raises questions regarding the ability of researchers to protect the privacy of research subjects whose genetic information is contained in public data sets. The researchers were able to identify almost 50 individuals whose genomes were sequenced as part of a study. The purpose of this study was to illustrate how "de-identified" genetic data can be identifiable and essentially improve the informed consent process by ensuring research subjects are fully informed of all risks, including risks to their privacy.

The study illustrates that it is possible to identify a research subject's identity through publicly-accessible genetic and genomic data. This may occur not only as a result of the genetic/genomic databases, but also by sharing personal information through social media, genealogy and government websites and health data-sharing models that enable information sharing between patients and researchers to improve patient care.

Interestingly, the *Science* study was published within days of the publication of the final HIPAA omnibus rule (the "Final Rule"), which implements various modifications to the HIPAA Privacy Rule under HITECH and the Genetic Information Nondiscrimination Act of 2008 ("GINA"). GINA forbids insurance companies or health plans from discriminating against members through reduced coverage or pricing and prohibits employers from making adverse employment decisions, based on a person's genetic predisposition to a disease. The Final Rule clarifies that genetic information is health information that is prohibited from being used or disclosed for underwriting purposes by group health plans, health insurance issuers (including HMOs), and issuers of Medicare supplemental policies. The effect of this rule is that most health plans are prohibited from using genetic information [including data obtained from public databases] for discriminatory practices. Though this provision should alleviate some concerns about the potential for misuse of genetic research data, there are still many open issues regarding discrimination by organizations not covered by GINA (such as life insurance companies) and possible stigmatization.

To address the privacy of genetic and genomic research data, organizations involved in clinical research partnerships will need to determine if and how genetic and genomic data will be shared with researchers and how such uses and data recipients will be identified in the informed consent form and authorization. Organizations must be especially cautious about including in the informed consent form language which suggests total anonymity or protection of the study subjects' privacy.

Organizations involved in clinical research should assess their study protocols that involve genetic or genomic data as well as all forms distributed to study subjects to ensure that issues of possible identification from genetic or genomic data are adequately taken into account.

For more information, please contact the authors **Linda A. Malek**, partner and co-chair of Moses & Singer's Healthcare Group, at 212.554.7832/lmalek@mosessinger.com, **Jill E. Anderson**, partner, at 212.554.7836/janderson@mosessinger.com, **Samuel J. Servello**, partner, at 212.554.7872/ sservello@mosessinger.com, or **JoAnna R. Nicholson**, associate, at jnicholson@mosessinger.com /212.554.7661.

MOSES & SINGER LLP

Since 1919, Moses & Singer has provided legal services to diverse businesses and to prominent individuals and their families. Among the firm's broad array of U.S. and international clients are leaders in banking and finance, entertainment, media, real estate, healthcare, advertising, and the hotel and hospitality industries. We provide cost-effective and result-focused legal services in the following primary areas:

- Accounting Law Practice
- Advertising
- Asset Protection
- Banking and Finance
- Business Reorganization, Bankruptcy and Creditors' Rights
- Corporate/M&A
- Corporate Trust
- Global Outsourcing and Procurement
- Healthcare
- Hospitality
- Income Tax
- Intellectual Property
- Internet/Technology
- Labor, Employment & Employee Benefits
- Legal Ethics & Law Firm Practice
- Litigation
- Matrimonial and Family Law
- Privacy and Cybersecurity
- Private Funds
- Promotions
- Real Estate
- Securities and Capital Markets
- Securities Litigation
- Sports & Entertainment
- Trusts and Estates
- White Collar Criminal Defense and Government Investigations

The Chrysler Building
405 Lexington Avenue
New York, NY 10174-1299
Tel: 212.554.7800 Fax: 212.554.7700

2200 Fletcher Avenue
Fort Lee, NJ 07024
Tel: 201.363.1210 Fax: 201.363.9210
Abraham Y. Skoff, Esq.
Managing Attorney for New Jersey

Moses & Singer LLP is the New York City law firm member of the MSI Global Alliance (MSI). MSI is one of the world's leading international alliances of independent legal and accounting firms, with over 250 member firms in 100 countries - www.msiglobal.org.