



**October 11, 2017**

As the Washington, DC area transitions from the heat of summer into the cooler Autumn months, there was an exciting transition for the NHGRI-Smithsonian *Genome: Unlocking Life's Code* exhibition. The exhibition has gone international – its North American tour took it to Canada at the end of September. In fact, I was just at [Science North](#) in Sudbury, Ontario to participate in a public symposium associated with the exhibition's international debut.

In other transitional news, long-time NHGRI extramural program director Dr. Jean McEwen retired from federal service last month. Since 1999, Jean has managed a robust grant portfolio within NHGRI's Ethical, Legal, and Social implications (or ELSI) Research Program, focusing on legal, regulatory, and public policy issues. I wish Jean all the best in her new endeavors!

This month's *The Genomics Landscape* features stories about:

- [The GTEx Project: Its Legacy Lives On](#)
- [NIH Seeks Input on Genomic Data Sharing Policy](#)
- [NIH-ACMG Fellowship in Genomic Medicine Program Management](#)
- [NIH Policy Changes for Clinical Trials](#)
- [NIH Policy Changes for Certificates of Confidentiality](#)
- [Jim Ostell Appointed NCBI Director](#)

All the best,

Watch here for current and upcoming locations of the Smithsonian-NHGRI exhibition "Genome: Unlocking Life's Code" as it tours North America!

Traveling Exhibition	
Current	Next
September 30, 2017 - January 1, 2018	January 28 - April 24, 2018
Science North Sudbury, Ontario	Rochester Museum and Science Center Rochester, New York
See <a href="http://unlockinglifescode.org">unlockinglifescode.org</a> for details	

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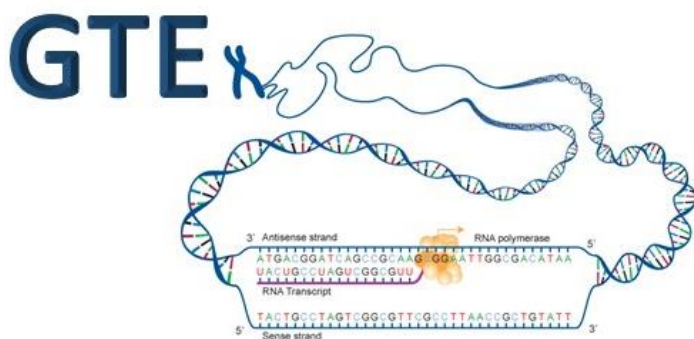
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## The GTEx Project: Its Legacy Lives On

The [Genotype-Tissue Expression \(GTEx\) Project](#) may be officially [complete](#), but its legacy certainly lives on given its success. GTEx's goal was to explore how variation in our genomes influence the expression of genes in different tissues.

In fitting with NIH's role in establishing resources for the scientific community, this high-achieving project met its lofty goal by accomplishing – for the first time – a freely and publicly available atlas for studying human genomic variation and its relationship to gene expression. This atlas is stimulating research for understanding the genomic basis for complex diseases and healthy states.



GTEx was [launched](#) in September 2010, and funding for the Project ended in fiscal year 2017. It was supported by the NIH Common Fund and administered by NHGRI, the National Institute of Mental Health, and the National Cancer Institute. Although funded by NIH, GTEx would not have been possible without the generosity of the families choosing to contribute biospecimens after the death of their loved ones. Through these invaluable gifts, researchers involved in the GTEx Consortium collected data from over 900 people. This included information from more than 53 different tissue types obtained via autopsy, organ donations, and tissue-transplant programs.

Using the data generated from these biospecimens, researchers analyzed gene expression within individual tissues and identified correlations between gene expression and variation in the regions of the genome that regulate that expression, which are known as expression quantitative trait loci (eQTLs). The identification of a catalog of such eQTLs, recently reported in the journal *Nature* by the GTEx Consortium, provides a valuable resource for studying the mechanisms by which genes are regulated.

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## NIH Seeks Input on Genomic Data Sharing Policy



Setting expectations for how genomic data are shared among researchers is important for sustaining public trust in the research enterprise and for maximizing the public benefit achieved through federal funding of research. The NIH [Genomic Data Sharing \(GDS\) Policy](#) provides a framework for the responsible sharing of genomic data generated from federally-funded research. NIH is updating how a specific type of research output, known as genomic summary results, can be accessed by researchers. NIH is proposing to make most genomic summary results more easily accessible. The relevant background and proposed changes can be found [here](#), and NIH is [requesting](#) comments from the scientific community and the public regarding the modifications. Responses to the [Request for Comment](#) will be accepted until October 20, 2017.

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## NIH-ACMG Fellowship in Genomic Medicine Program Management



Under NHGRI's leadership, NIH and the American College of Medical Genetics and Genomics (ACMG) recently established a fellowship in Genomic Medicine Program Management – a two-year opportunity for qualified physicians to acquire experience for leading genomic medicine research and implementation programs at the NIH, major medical centers, and other organizations. The goal of the program is to increase the pool of physicians who can manage research and implementation programs in genomic medicine. The first fellow, Jennifer Krupp, M.D., [started](#) in September. Qualified applicants must have graduated from medical or osteopathic school, be U.S. citizens, and be licensed to practice medicine in the United States. Applications for fellows wishing to start in the program in the Summer 2018 are due by December 1; additional details can be found [here](#).

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In addition to generating this atlas, GTEx also aimed to study the donor-consent process. This work sought to better understand how participating in the study might affect the attitudes, beliefs, and feelings of donors and the families of deceased donors.

Although the GTEx atlas is almost complete, and primary data analysis will soon be finished, research will continue through its biobank of tissue, DNA, and RNA samples, which is housed at the Broad Institute and can be accessed by research teams around the world. The project also created a database that allows users to view and download GTEx summary data through the [GTEx Portal](#), and individual-level data types can be accessed in [NIH's database of Genotypes and Phenotypes \(dbGaP\)](#).



One hallmark of GTEx was its annual community meetings. Open to the scientific community, these meetings showcased a melting pot of ideas for using GTEx data in biomedical research. The GTEx Consortium held its [final meeting on June 28, 2017](#) in Rockville, Maryland to highlight the final dataset, the tools and methods developed to analyze these data, and the wide range of insights gained to date from using the data.

NIH continues to capitalize on the vast knowledgebase that has been created by GTEx. For example, plans to extend this resource through the Enhancing GTEx (eGTEx) Project have been underway since 2013. eGTEx combines gene-expression studies with additional measurements (e.g., protein expression), which are being conducted on the same tissue samples as in GTEx. These additional data will provide a more complete reference about functional consequences of genomic differences, giving researchers a more detailed picture of how the genome contributes to human health and disease.



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### ***NIH Policy Changes for Clinical Trials***

Does your human subjects research study meet the NIH Definition of a clinical trial?

There are upcoming [changes](#) to the policies that guide the stewardship of NIH-funded clinical trials. Specifically, there will be a number of new expectations for clinical trials that come into effect for applications due on or after January 25, 2018. These changes are part of an ongoing effort to improve transparency and oversight of NIH-funded clinical trials that began in 2014, when NIH first clarified and broadened how it defines a clinical trial. NIH has developed a new [Clinical Trial Requirements web page](#) to provide the information that investigators need to be in compliance with the new policies. The web page includes case studies, Frequently Asked Questions, and an interactive tool for determining whether a study meets the definition of a clinical trial.

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### ***NIH Policy Changes for Certificates of Confidentiality***



Based on language included in the [21<sup>st</sup> Century Cures Act](#) and the need to provide consistent and robust privacy protection for research participants, NIH recently released a new Certificates of Confidentiality Policy. The new policy requires that [Certificates of Confidentiality](#) (or CoCs) are issued to institutions where a relevant human subjects research study is conducted. The new policy also prohibits researchers from disclosing names or other identifying characteristics of research subjects in response to legal demands (e.g. a subpoena). Previously, NIH issued CoCs to cover studies collecting sensitive data about research subjects upon request from researchers; however, as of October 1, 2017, NIH-funded researchers are automatically issued a CoC for research covered by the policy. Compliance with the requirements of the law will become a term and condition of award for grant recipients collecting these types of data. More information on the new policy can be found [here](#).

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**Jim Ostell  
Appointed  
NCBI Director**



In September, Jim Ostell, Ph.D., was [appointed](#) the new Director of the [National Center for Biotechnology Information](#) (NCBI), a part of the National Library of Medicine. Dr. Ostell has been with NCBI since its inception in 1988. Prior to his appointment as NCBI Director, he served as Chief of the NCBI Information Engineering Branch, where he was responsible for designing, developing, building, and deploying NCBI's production resources. NCBI supports and maintains biomedical databases and computing tools to better understand genes and their role in health and disease. NHGRI and NCBI interact in numerous ways related to the storage and analysis of genomic data.

**Spotlight  
on the  
All of Us  
Research  
Program**



- *All of Us* Director's Corner – [Closed Beta Updates and EHR Consent](#).
- [All of Us Journey](#) hits the road.
- Meet *All of Us* Director of Scientific Programs – [Dr. Joni Rutter](#).
- Ensuring that diverse communities [participate](#) in the *All of Us* Research Program.
- In an [Associated Press video](#), Dr. Collins discusses the *All of Us* Research Program.

**Genomics Research**

[NHGRI Researchers and Collaborators Identify Noonan Syndrome in Diverse People](#)

[Notable Accomplishments in Genomic Medicine](#)

**New Videos**

[National Advisory Council for Human Genome Research – September 2017](#)

[Risk, Race & Resilience: Three Dimensions of Health Disparities - Herman Taylor](#)

[NHGRI's Oral History Collection: Interview with Michael Gottesman](#)

[The Gene Doctors on PBS](#)

**Requests for Input**

[Accessing Genomic Summary Results](#)

[Return of Individual-Specific Research Results in Research Labs](#)

**Funding Opportunities**

Ethical, Legal, and Social Implications (ELSI) of Genomics [Research Project Grant Program \(R01\)](#), [Small Research Grant Program \(R03\)](#), and [Exploratory/Development Research Grant Program \(R21\)](#)

[Comparative Genomics Research Program \(R01-Clinical Trial Not Allowed\)](#)

Research on Transgender Health [R21](#) and [R01](#)

Human Heredity and Health in Africa (H3Africa): Ethical, Legal, and Societal Issues [Collaborative Centers](#) and [Research Program](#)

**Funding News**

[Assistance Available to Institutions Impacted by Hurricane Harvey](#)

[NIH Natural Disaster Policy - Hurricane Irma](#)

[Policy Supporting the Next Generation Researcher Initiative](#)

[Additional Travel Funds for Diversity Action Plan Participants in "Initiative to Maximize Research Education in Genomics"](#)

**NIH & NHGRI News**

[New Toolkit Helps Nurses Use Genomics in Patient Care](#)

[Meet ASHG/NHGRI Genetics & Public Policy Fellow Nikki Meadows](#)

[NCI Scientists Receive Lasker-DeBakey Clinical Medical Research Award](#)

[Unlocking Life's Code: September 2017 Newsletter](#)

[Francis Collins Speaks to Diane Rehm about Gene Editing, Regenerative Medicine, and Immunotherapy](#)

[Expanding Our View of the Human Microbiome](#)

NIH Grantees Win 2017 Nobel Prize in [Physiology or Medicine](#) and in [Chemistry](#)

[Precision Medicine: Making Warfarin Safer](#)

[NIH to fund Centers of Excellence on Minority Health and Health Disparities](#)

**Upcoming Webinar**

[NIH Single IRB & Exceptions Process Webinar – October 18](#)

