National Human Genome Research Institute

The Forefront of Genomics®

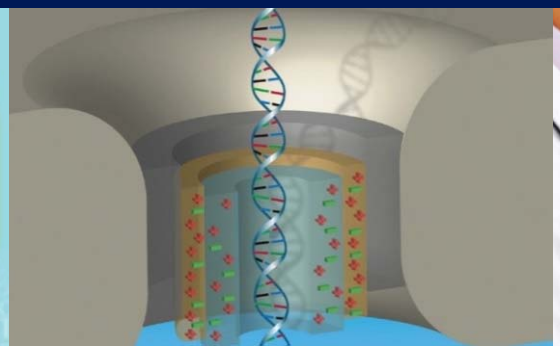
DIRECTOR'S REPORT

Eric Green, M.D., Ph.D.

Director, NHGRI

February 2019





Director's Report-Related Documents: February 2019

Director's Report 

Director's Report 

No.	Relevant Documents
1	**'Genomics2020' Strategic Planning Process** 'Genomics2020' Website 'Genomics2020' News and Events Calendar 'Genome to Phenotype' Workshop Videocast
2	Population Descriptors in Genomics and Biomedical Research
3	Mourning the Loss of Steve Katz
4	New Director, National Institute of Biomedical Imaging and Bioengineering
5	New Director, White House Office of Science and Technology Policy
6	Genomic Data Sharing Policy Update: Access to Genomic Summary Results (GSR)
7	NIH Implementation of Common Rule

genome.gov/DirectorsReport

Document #

Open Session Presentations

- **Presentation: A Clinical Imperative – Genomics, Population Health, and Precision Health at Geisinger**

  Hunt Willard

- **Concept Clearance: Electronic Medical Records and Genomics (eMERGE) – Comprehensive Genomic Risk Assessment and Management**

  Teri Manolio

- **Concept Clearance: Centers of Excellence in ELSI Research**

  Joy Boyer

Open Session Presentations

- **Report: NACHGR Data Science Working Group**
  Trey Ideker
- **Report: NACHGR Community Engagement in Genomics Working Group**
  Gwen Darien
- **Report: Clinical Genomics (ClinGen) Resource**
  Erin Ramos & Sharon Plon
- **Report: NHGRI Triennial Inclusion Report**
  Christine Chang

Director's Report Outline

I. General NHGRI Updates

II. General NIH Updates

III. General Genomics Updates

IV. NHGRI Extramural Research Program

V. NIH Common Fund/Trans-NIH

VI. NHGRI Division of Policy, Communications, and Education

VII. NHGRI Intramural Research Program

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Departure of Director, NHGRI Division of Policy, Communications, and Education

Laura Lyman Rodriguez, Ph.D.

Retirement of NHGRI Program Director

Jeff Struewing, M.D.

‘Genomics2020’ Strategic Planning Process

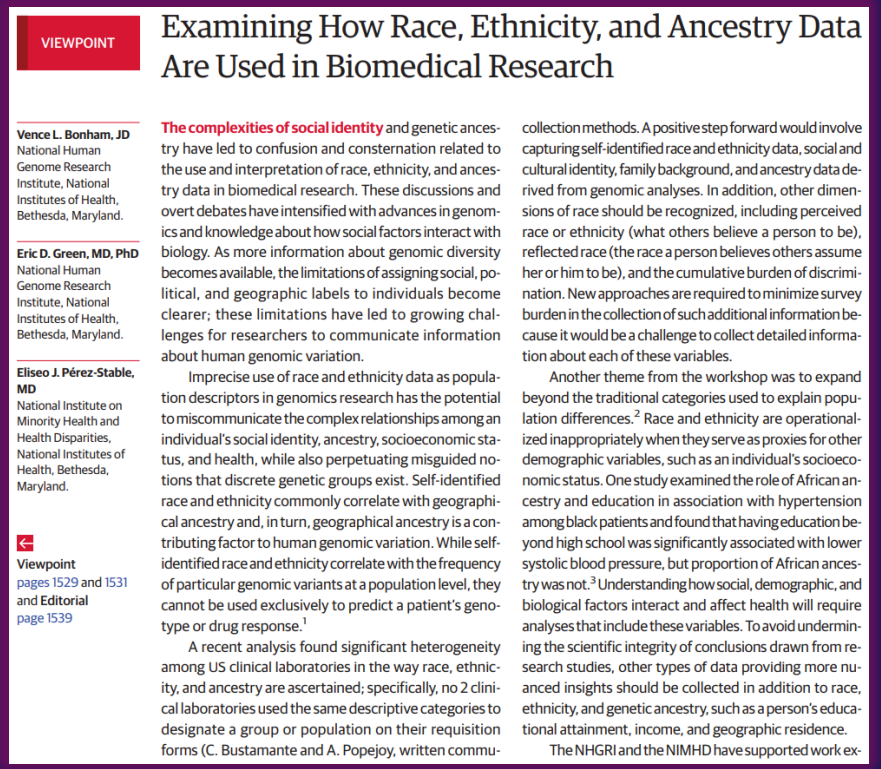
Recent Events:

- Town Hall in Atlanta, GA
- Nine satellite meetings/sessions
- ‘*Genome to Phenotype*’ Workshop

Document 1

Population Descriptors in Genomics and Biomedical Research

- Increase scientific rigor in collecting data describing participants, especially in clinical settings
- Ensure collected data reflect the multidimensional nature of a person's identity
- New trans-NIH working group established to identify next steps



VIEWPOINT

Examining How Race, Ethnicity, and Ancestry Data Are Used in Biomedical Research

Vence L. Bonham, JD
National Human Genome Research Institute, National Institutes of Health, Bethesda, Maryland.

Eric D. Green, MD, PhD
National Human Genome Research Institute, National Institutes of Health, Bethesda, Maryland.

Eliseo J. Pérez-Stable, MD
National Institute on Minority Health and Health Disparities, National Institutes of Health, Bethesda, Maryland.

Viewpoint
pages 1529 and 1531
and **Editorial**
page 1539

The complexities of social identity and genetic ancestry have led to confusion and consternation related to the use and interpretation of race, ethnicity, and ancestry data in biomedical research. These discussions and overt debates have intensified with advances in genomics and knowledge about how social factors interact with biology. As more information about genomic diversity becomes available, the limitations of assigning social, political, and geographic labels to individuals become clearer; these limitations have led to growing challenges for researchers to communicate information about human genomic variation.

Imprecise use of race and ethnicity data as population descriptors in genomics research has the potential to miscommunicate the complex relationships among an individual's social identity, ancestry, socioeconomic status, and health, while also perpetuating misguided notions that discrete genetic groups exist. Self-identified race and ethnicity commonly correlate with geographical ancestry and, in turn, geographical ancestry is a contributing factor to human genomic variation. While self-identified race and ethnicity correlate with the frequency of particular genomic variants at a population level, they cannot be used exclusively to predict a patient's genotype or drug response.[1]

A recent analysis found significant heterogeneity among US clinical laboratories in the way race, ethnicity, and ancestry are ascertained; specifically, no 2 clinical laboratories used the same descriptive categories to designate a group or population on their requisition forms (C. Bustamante and A. Popejoy, written communication methods. A positive step forward would involve capturing self-identified race and ethnicity data, social and cultural identity, family background, and ancestry data derived from genomic analyses. In addition, other dimensions of race should be recognized, including perceived race or ethnicity (what others believe a person to be), reflected race (the race a person believes others assume her or him to be), and the cumulative burden of discrimination. New approaches are required to minimize survey burden in the collection of such additional information because it would be a challenge to collect detailed information about each of these variables.

Another theme from the workshop was to expand beyond the traditional categories used to explain population differences.[2] Race and ethnicity are operationalized inappropriately when they serve as proxies for other demographic variables, such as an individual's socioeconomic status. One study examined the role of African ancestry and education in association with hypertension among black patients and found that having education beyond high school was significantly associated with lower systolic blood pressure, but proportion of African ancestry was not.[3] Understanding how social, demographic, and biological factors interact and affect health will require analyses that include these variables. To avoid undermining the scientific integrity of conclusions drawn from research studies, other types of data providing more nuanced insights should be collected in addition to race, ethnicity, and genetic ancestry, such as a person's educational attainment, income, and geographic residence.

The NHGRI and the NIMHD have supported work ex-

Document 2

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Mourning the Loss of Steve Katz

Bob Carter, M.D.

Document 3

New Director, National Institute of Biomedical Imaging and Bioengineering

Bruce Tromberg, Ph.D.

NIH NIBIB

Document 4

New Director, White House Office of Science and Technology Policy

Kelvin Droegemeier, Ph.D.

Document 5

Genomic Data Sharing Policy Update: Access to Genomic Summary Results (GSR)

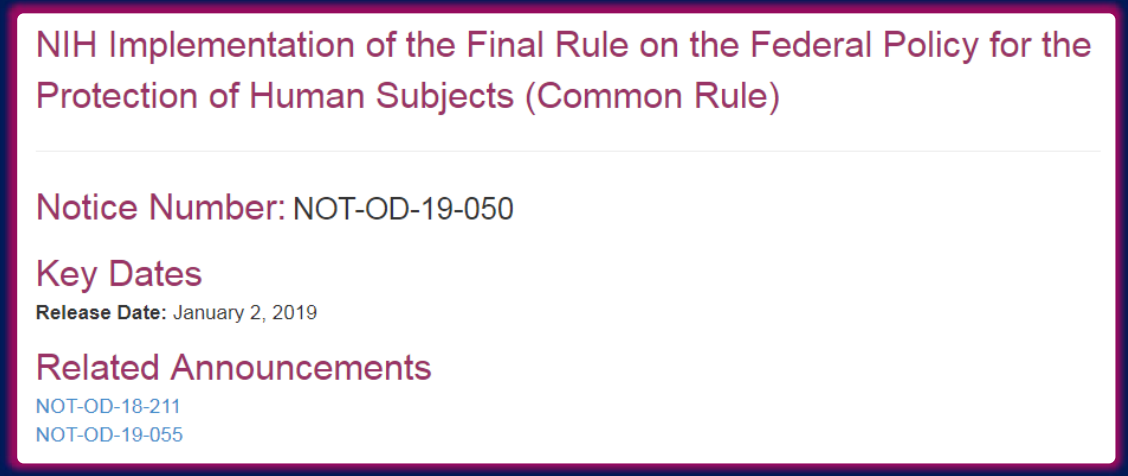
National Institutes of Health
Office of Science Policy

Genomic Data Sharing

- **November 2018: NIH updated the access procedures for GSR under the Genomic Data Sharing Policy**
- **Beginning May 2019: GSR from most genomic studies will be possible through open access**
- **GSR designated as 'sensitive' by the submitting institution will remain in controlled access**

Document 6

NIH Implementation of Common Rule



NIH Implementation of the Final Rule on the Federal Policy for the Protection of Human Subjects (Common Rule)

Notice Number: NOT-OD-19-050

Key Dates

Release Date: January 2, 2019

Related Announcements

NOT-OD-18-211
NOT-OD-19-055

- **Common Rule implementation began on January 21, 2019**
- **Changes to IRB review and requirement to post clinical trial informed consent forms**
- **Evaluate technologies and techniques on whether they generate "identifiable private information"**

Document 7

NIH Workshop: Harnessing Artificial Intelligence and Machine Learning to Advance Biomedical Research

Document 8

Fiscal Year 2019 Appropriations

	Fiscal Year 2018 Labor-HHS Appropriation	Fiscal Year 2019 Labor-HHS Appropriation	$ Increase	% Increase
NIH	$37.1 B	$39.1 B	**~$2.0 B**	~5.1%
NHGRI	$556 M	$575 M	**~$19 M**	~3.3%

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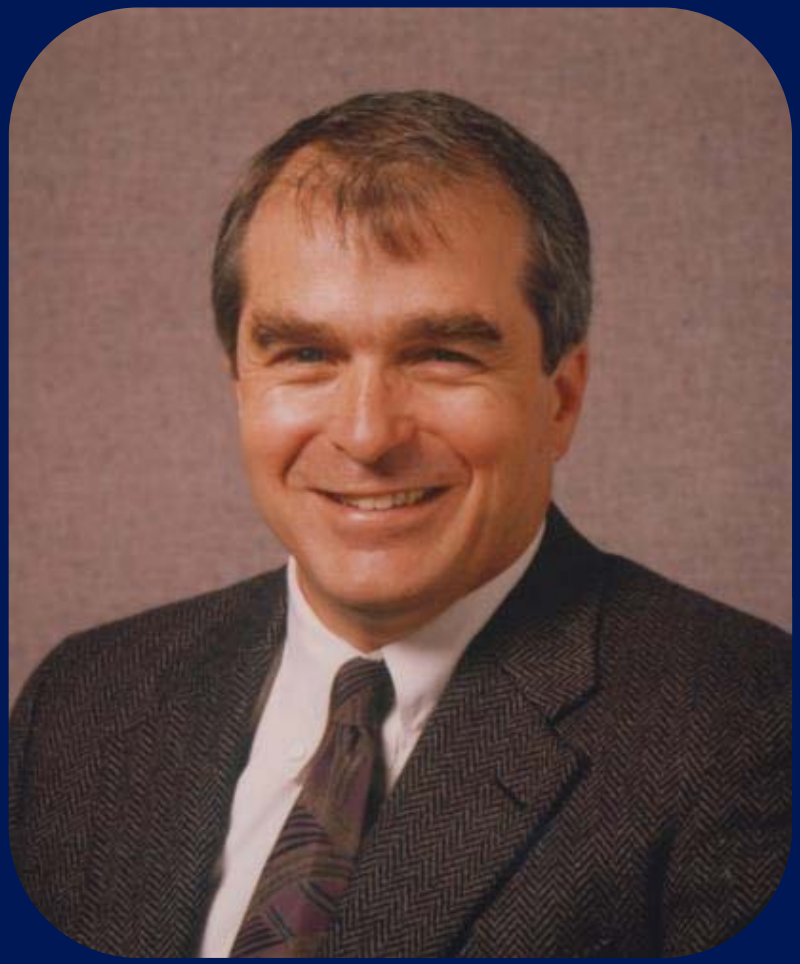
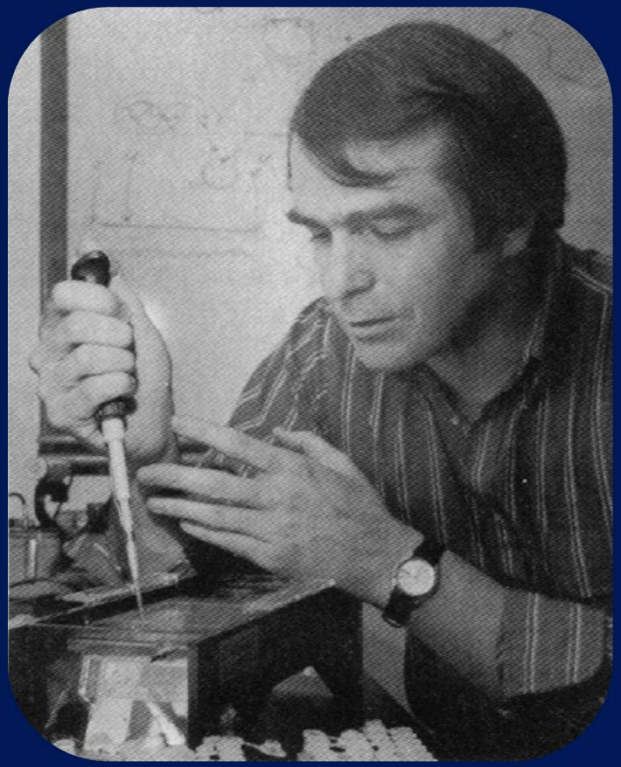
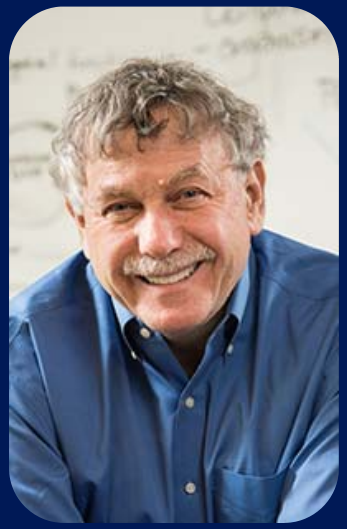
Mourning the Loss of Ray White





Document 9

2018 American Society of Human Genetics Awards



Eric Lander

Sekar Kathiresan

Jim Lupski

Mary-Claire King

Andy Adey

ASHG2018
SAN DIEGO • OCTOBER 16-20, 2018
SHARING DISCOVERIES. SHAPING OUR FUTURE.

Document 10

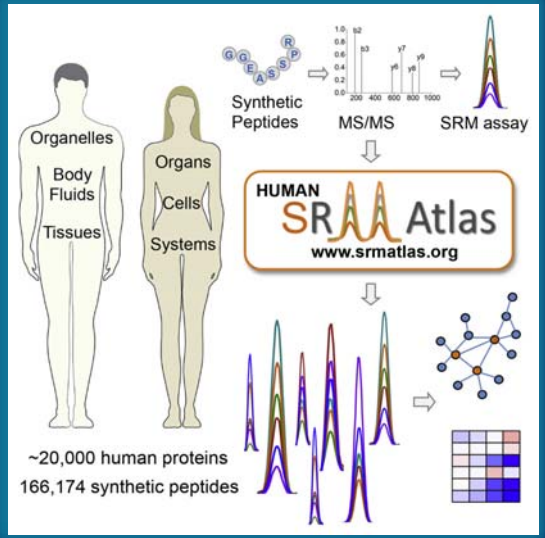
Elected to National Academy of Medicine

Andrea Califano
Bill Gahl
Josh Gordon
Bob Kingston
Brad Malin
Lucila Ohno-Machado
Gene Robinson
Charles Rotimi
Stu Schreiber

Elected to AAAS

Richard Axel
Andreas Baxevanis
Wayne W. Grody
Pavel Pevzner
Jay Shendure

2018 Human Proteome Organization Award



HUPO
HUMAN PROTEOME ORGANIZATION
translating the code of life

Ulrike Kusebauch, Ph.D.

Science's 2018 Breakthrough of the Year Runners Up

Forensic genealogy comes of age

Gene-silencing drug approved

How cells marshal their contents

Document 14

The Scientist's Top Ten Innovations of 2018

1. Tapestri Precision Genomics Platform by Mission Bio
2. Chromium Immune Repertoire Profiling Solution by 10X Genomics
3. Dharmacon Edit-R Fluorescent Cas9 Nuclease mRNA by Horizon Discovery
4. MAD7 Enzyme by Inscripta
5. BD AbSeq Assay by BD Life Sciences

Genomes In The News…

Document 16

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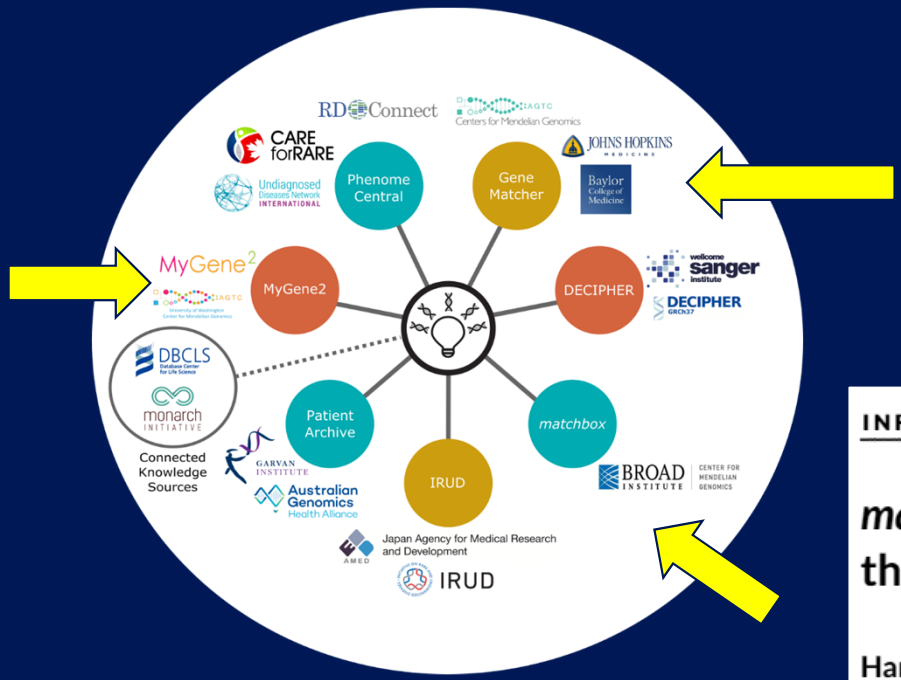
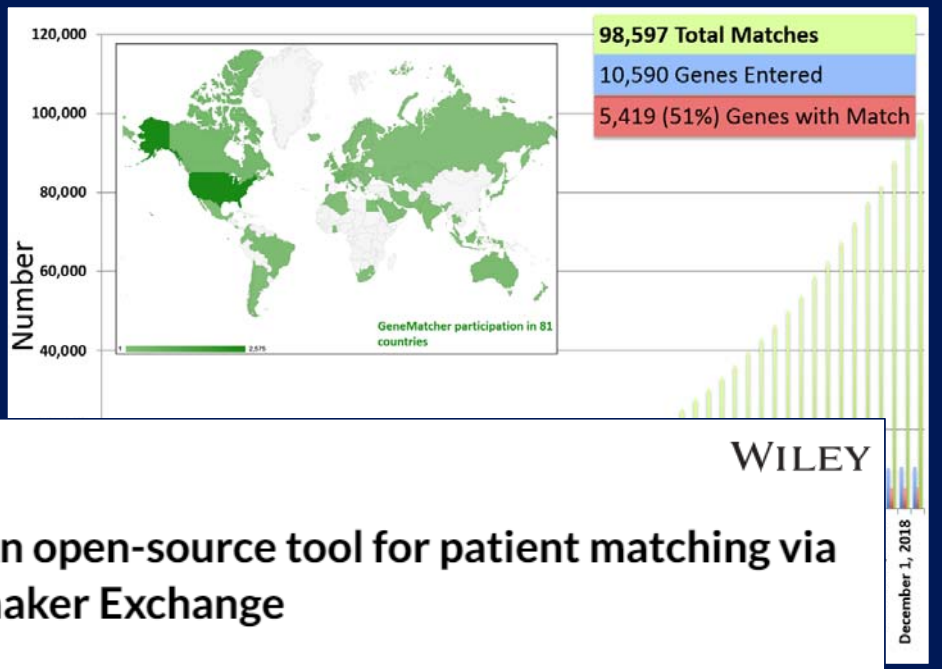
Genome Sequencing Program

Centers for Mendelian Genomics





INFORMATICS

WILEY

***matchbox*: An open-source tool for patient matching via the Matchmaker Exchange**

Harindra Arachchi[1,2] | Monica H Wojcik[1,3] | Benjamin Weisburd[1] |
Julius O. B. Jacobsen[4] | Elise Valkanas[1] | Samantha Baxter[1] | Alicia B. Byrne[1,5,6]
Anne H. O'Donnell-Luria[1,3] | Melissa Haendel[7,8] | Damian Smedley[4] |
Daniel G. MacArthur[1,2,9] | Anthony A. Philippakis[2] | Heidi L. Rehm[1,2,9]

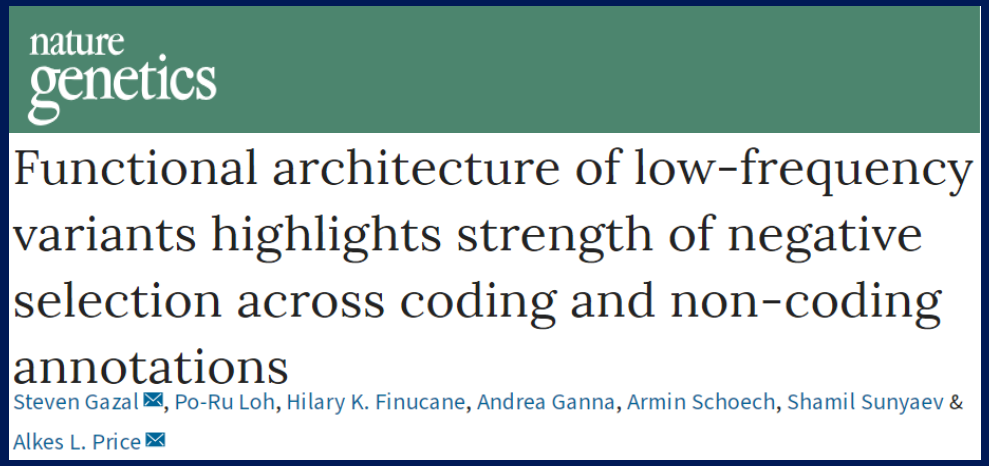
Genome Sequencing Program

Centers for Common Disease Genomics

Disease Category	Sample Type	Samples Sequenced	Samples Projected By End of Y5
Cardiovascular	Genomes	45,414	90,258
	Exomes	35,283	172,283
Immune-Mediated	Genomes	9,749	9,749
	Exomes	13,535	37,535
Neuropsychiatric	Genomes	18,251	26,651
	Exomes	29,071	44,071
TOTAL GENOMES			**126,658**
TOTAL EXOMES			**253,889**

Genome Sequencing Program

Analysis Centers and Coordinating Center



Follow @NHGRI_GSP

Document 17

Human Genome Reference Program
Funding Opportunity Announcements

- **HG-19-004: Human Genome Reference Center (U41)**
- **HG-19-002: High Quality Human Reference Genomes (U01)**
- **HG-19-003: Research and Development for Genome Reference Representations (U01)**
- **Applications will be accepted from March 2 to April 2, 2019**
- **Webinar: Friday, March 8 from 11:00 AM – 1:00 PM ET**

Technology Development Program

- **Novel Nucleic Acid Sequencing Technology Development**

  RFA-HG-18-001 (R01, also linked R21 and R43/44)

  Applications due June 27, 2019

- **Advanced Genomic Technology Development Meeting**

  Northeastern University

  Grantee Meeting: May 29-30, 2019

  Public Meeting: May 31, 2019

ENCyclopedia Of DNA Elements (ENCODE)

- ENCODE Consortium Meeting (January 2019)
- Accessibility and Utilization of ENCODE Data Workshop at ASHG (October 2018)
- Research and Applications Users Meeting in Seattle (July 2019)

PsychENCODE

RESEARCH | PSYCHENCODE

RESEARCH ARTICLE SUMMARY

PSYCHIATRIC GENOMICS

Transcriptome-wide isoform-level dysregulation in ASD, schizophrenia, and bipolar disorder

RESEARCH | PSYCHENCODE

RESEARCH ARTICLE SUMMARY

PSYCHIATRIC GENOMICS

Comprehensive functional genomic resource and integrative model for the human brain

RESEARCH ARTICLE | CELLULAR NEUROSCIENCE

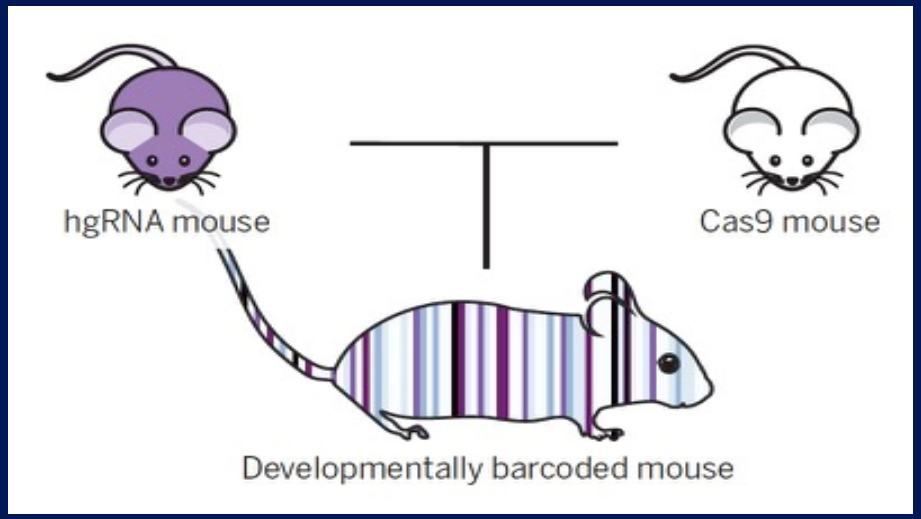
Using 3D epigenomic maps of primary olfactory neuronal cells from living individuals to understand gene regulation

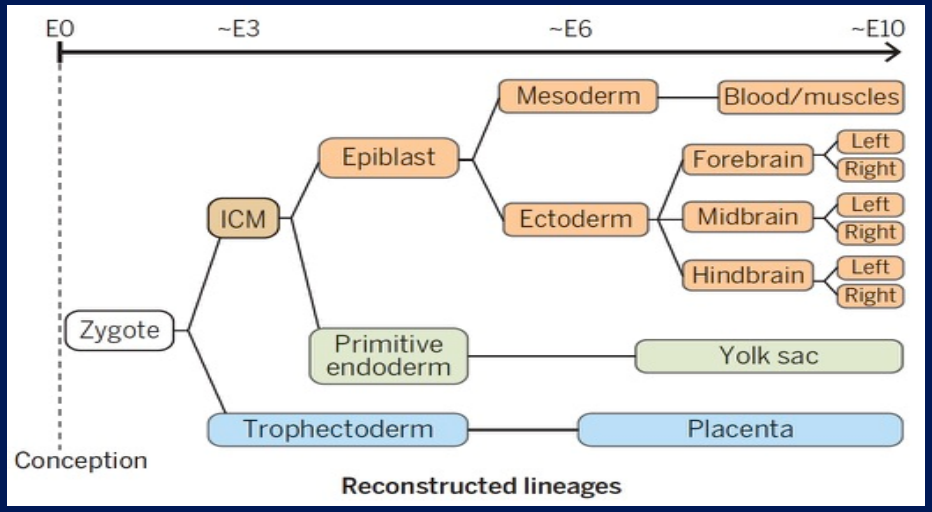
Document 20

Centers of Excellence in Genomic Science (CEGS)

Developmental barcoding of whole mouse via homing CRISPR

Reza Kalhor*, Kian Kalhor, Leo Mejia, Kathleen Leeper, Amanda Graveline, Prashant Mali, George M. Church*

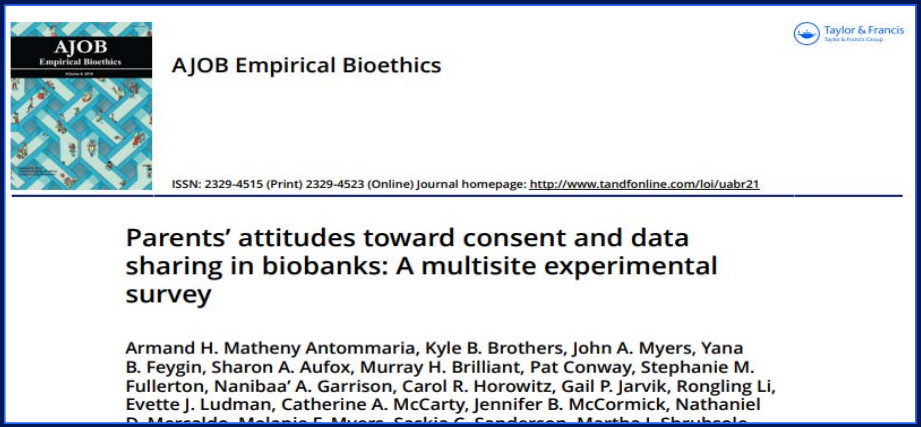




Document 21

eMERGE network

ELECTRONIC MEDICAL RECORDS AND GENOMICS

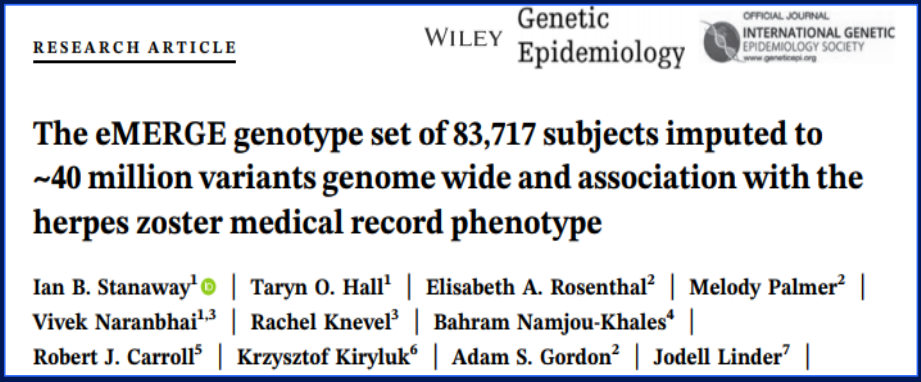


AJOB Empirical Bioethics

ISSN: 2329-4515 (Print) 2329-4523 (Online) Journal homepage: http://www.tandfonline.com/loi/uabr21

Parents' attitudes toward consent and data sharing in biobanks: A multisite experimental survey

Armand H. Matheny Antommaria, Kyle B. Brothers, John A. Myers, Yana B. Feygin, Sharon A. Aufox, Murray H. Brilliant, Pat Conway, Stephanie M. Fullerton, Nanibaa' A. Garrison, Carol R. Horowitz, Gail P. Jarvik, Rongling Li, Evette J. Ludman, Catherine A. McCarty, Jennifer B. McCormick, Nathaniel



RESEARCH ARTICLE

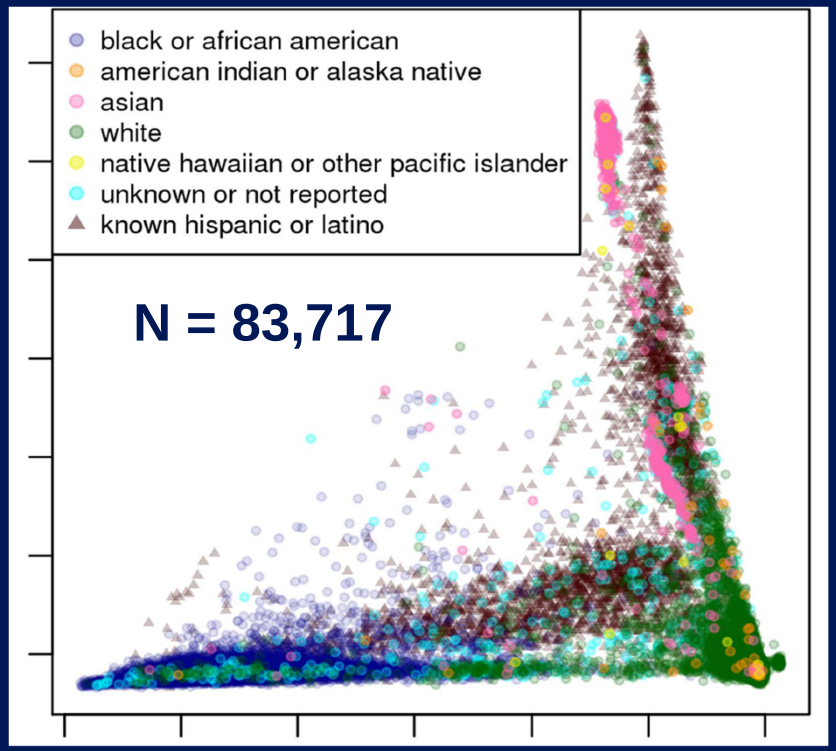
WILEY Genetic Epidemiology

OFFICIAL JOURNAL INTERNATIONAL GENETIC EPIDEMIOLOGY SOCIETY

The eMERGE genotype set of 83,717 subjects imputed to ~40 million variants genome wide and association with the herpes zoster medical record phenotype

Ian B. Stanaway[1] | Taryn O. Hall[1] | Elisabeth A. Rosenthal[2] | Melody Palmer[2] | Vivek Naranbhai[1,3] | Rachel Knevel[3] | Bahram Namjou-Khales[4] | Robert J. Carroll[5] | Krzysztof Kiryluk[6] | Adam S. Gordon[2] | Jodell Linder[7] |

Principal Components Analysis (PCA) Examining Ancestry of eMERGE Phases I-III Imputation

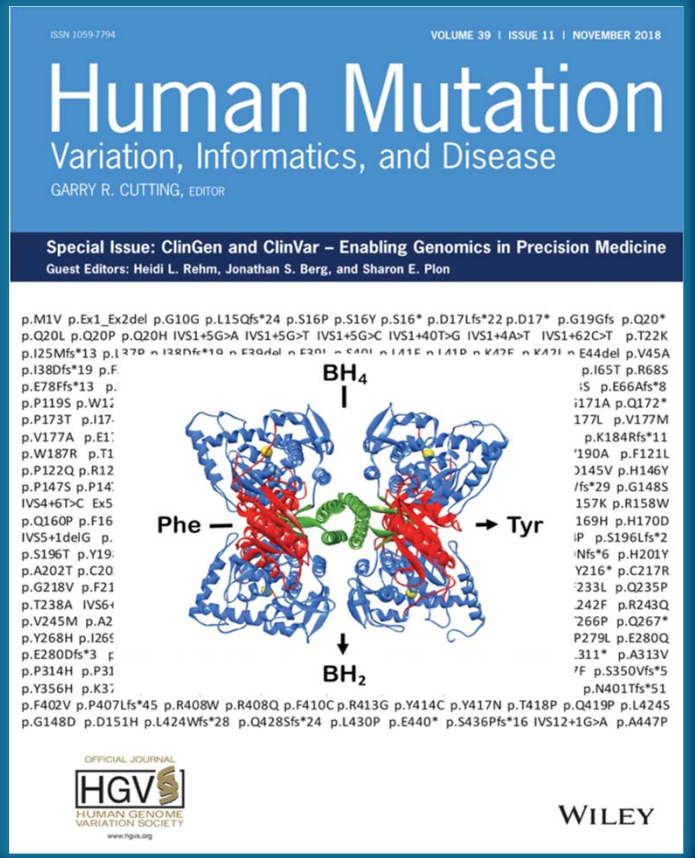


Document 22

Clinical Genome Resource (ClinGen)

ClinGen
Clinical Genome Resource

- *Human Mutation* special issue featured ClinGen and ClinVar
- Published October 11, 2018
- Guest editors: Jonathan Berg, Heidi Rehm, and Sharon Plon
- 25 papers



FDA Recognizes ClinGen as Genetic Variant Database

NCBI ClinVar

Gene(s)	Condition(s)	Clinical significance (Last reviewed)	Review status
KCNQ4	Nonsyndromic hearing loss and deafness, not specified	Likely benign (Sep 28, 2018)	reviewed by expert panel FDA Recognized Database
KCNQ4	Nonsyndromic hearing loss and deafness, not specified	Likely pathogenic (Sep 10, 2018)	reviewed by expert panel FDA Recognized Database
KCNQ4	DFNA 2 Nonsyndromic Hearing Loss, Nonsyndromic hearing loss and deafness	Pathogenic (Sep 11, 2018)	reviewed by expert panel FDA Recognized Database

- Announced on December 4, 2018
- First curation effort to be recognized
- FDA-recognized genomic variants available in ClinVar

Clinical Sequencing Evidence-Generating Research (CSER) Program

Recruitment Update:

Overall projected CSER race/ethnicity	Count	%
Hispanic/Latino	1615	25.1%
Black/ African American	2337	36.3%
American Indian/Alaska Native	74	1.2%
Asian	349	5.4%
Native Hawaiian/Pacific Islander	10	0.2%
More than one race	319	4.9%
White (non-Hisp.)	1742	27.0%
Total sequenced participants	6446	
Total race/ethnic diversity	73%	
Total diversity	79%	

Lessons Learned:

- Importance of engaging recruiting providers
- Potentially lower decline rates than expected

Joint CSER-eMERGE Meeting

cser
Clinical Sequencing Evidence-Generating Research

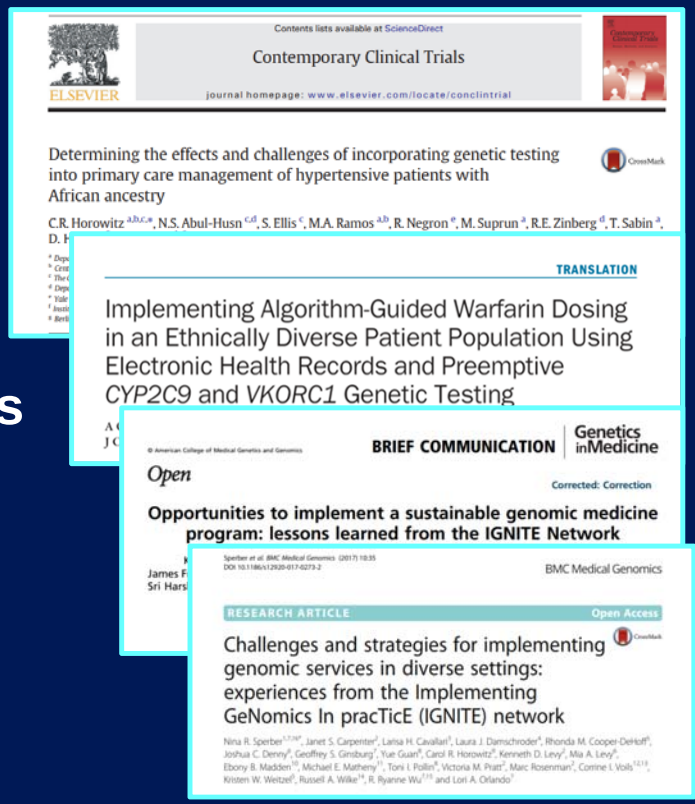
emerge network
ELECTRONIC MEDICAL RECORDS & GENOMICS

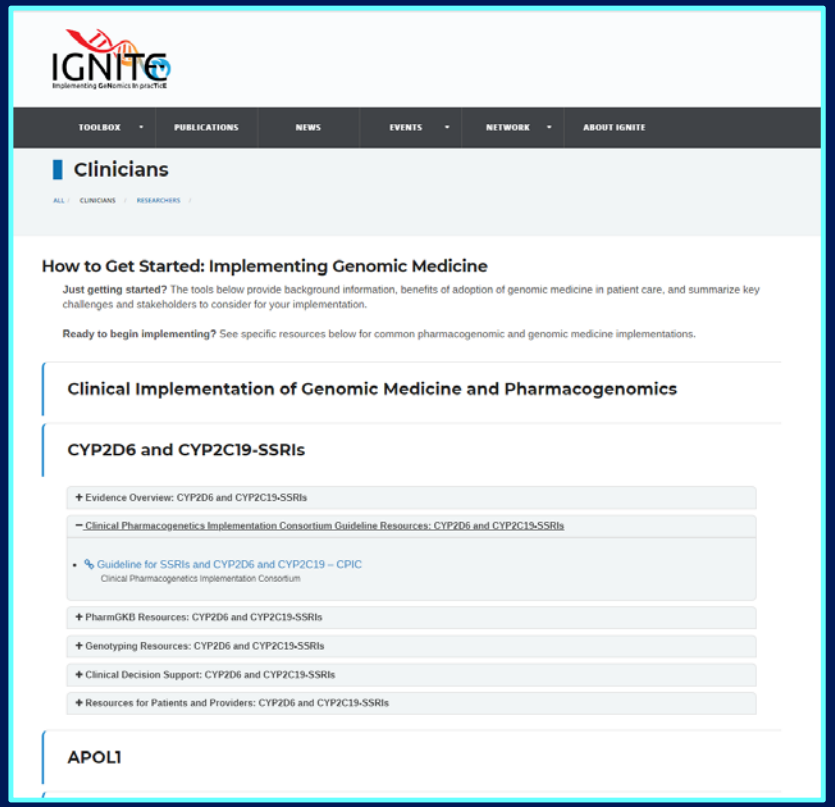
- Selection and performance of harmonized measures and outcomes
- Cascade testing of relatives
- Provider engagement
- Tools for variant classification
- Outcomes and healthcare utilization
- Scalable approaches to patient and provider interactions
- ELSI issues

Implementing GeNomics In pracTicE (IGNITE) I

133 publications

41 manuscripts submitted



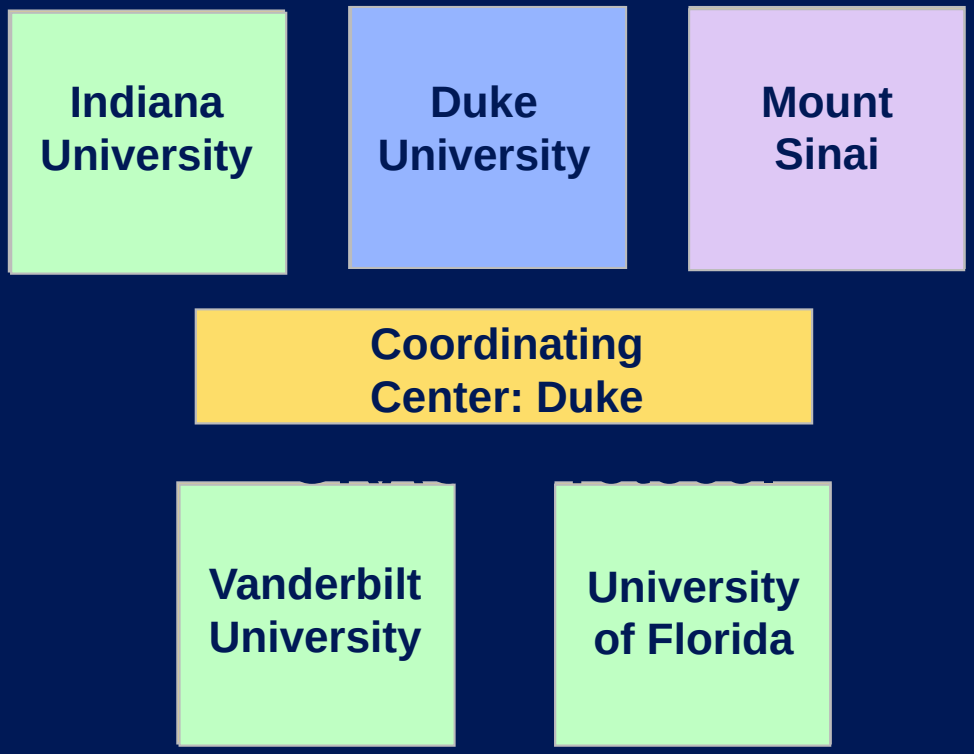


Final IGNITE I meeting April 16, 2019

Document 25

Implementing GeNomics In pracTicE (IGNITE) II: Pragmatic Clinical Trials

- Protocol Review Committee met in October & December 2018
- Prioritized Protocols:
  - Harmonized PGx Protocol
  - GUARDD-US
  - GRACE
- Next:
  - Data Safety Monitoring Board
  - Recruitment to begin in mid/late 2019



Newborn Sequencing In Genomic medicine and public HealTh (NSIGHT)

AJHG

Interpretation of Genomic Sequencing Results in Healthy and Ill Newborns: Results from the BabySeq Project

2019 Jan 3;104(1):76-93

- **159 newborns (well nursery and NICU recruitment)**
- **9.4% (15/159) revealed risk of childhood-onset disease**
- **5% (8/159) pharmacogenomic and 88% (140/159) recessive childhood-onset disorder carrier status**

BABYSEQ™

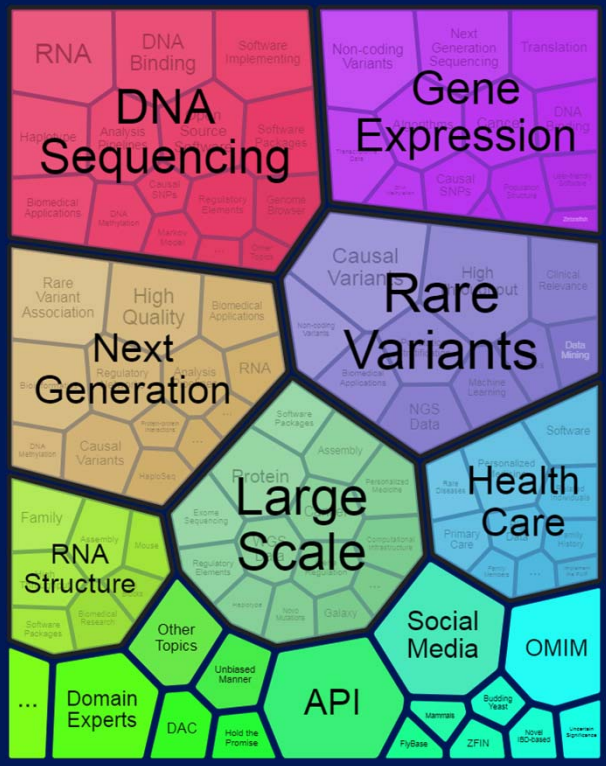
Computational Genomics and Data Science Program

- **First round of applications received under PAR-18-844 (R01) and PAR-18-843 (R21)**

  Next receipt date: July 16, 2019

- **SBIR PAR-19-061 released in December 2018**

  Next receipt date: April 5, 2019



Computational Genomics and Data Science Program

ALLIANCE of GENOME RESOURCES

2018 AGR All-Hands Meeting

Recent Accomplishments

- Common orthology set
- Uniform representations of gene-to-human disease associations
- Display of harmonized gene function, expression, and interactions data

Computational Genomics and Data Science Program

D330–D338 *Nucleic Acids Research, 2019, Vol. 47, Database issue*
doi: 10.1093/nar/gky1055

The Gene Ontology Resource: 20 years and still GOing strong

The Gene Ontology Consortium†

Recent Accomplishments and Current Efforts

- **Improved framework for gene function models**
- **Revision of the GO Resource and improved integration with external ontologies**
- **GO ribbon: a configurable tool for visualizing GO annotations**

5th iDASH Genomic Privacy Challenge

- October 2018 (San Diego)
- Challenge Tasks: (1) Blockchain for distributed data, (2) Secure GWAS using homomorphic encryption, and (3) Secure search of DNA segments in databases
- Third task aims to help protect the privacy of genealogical searches

ELSI Research Program

Document 29

Small Business Program

SBIR · STTR
America's Seed Fund™

- ~$15 million dollars in Fiscal Year 2018
- 19 Phase I Proof of Principle awards
- 5 Phase II Pre-Commercialization awards

  Genturi: device for sizing DNA
  Cell Microsystems: single-cell imaging and RNA-Seq
  JBS Science: urine DNA-isolation kit
  Genomenon: high-throughput computational genomics analysis
  Frameshift Labs: computational genomics access, management, visualization and analysis

Research Training and Career Development

New Diversity Action Plan Awardees

Principal Investigator	Institution	NHGRI Area
Joseph Yost	U. Utah	Genomic Science
Maja Bucan and Junhyong Kim	U. Pennsylvania	Genomic Science
Bruce Korf	U. Alabama at Birmingham	Genomic Medicine
Paul Spicer	U. Oklahoma	ELSI
Jeff Botkin and James Tabery	U. Utah	ELSI
Debra Mathews	Johns Hopkins	ELSI

Research Training and Career Development

- **Research supplements promoting diversity**

> Notice to Encourage Eligible NHGRI Awardees to Apply for PA-18-906 "Research Supplements to Promote Diversity in Health-Related Research
>
> Notice Number: NOT-HG-19-010

- **Supplements must be submitted at least 90 days prior to anticipated need and no later than May 15, 2019**

NHGRI Extramural Research Highlights

SSRN
SOCIAL SCIENCE RESEARCH NETWORK

WHO KNOWS WHAT, AND WHEN?: A SURVEY OF THE PRIVACY POLICIES PROFFERED BY U.S. DIRECT-TO-CONSUMER GENETIC TESTING COMPANIES*

*James W. Hazel*** & *Christopher Slobogin****

Systematic analysis of complex genetic interactions

Elena Kuzmin[1,2,*,†], Benjamin VanderSluis[3,*], Wen Wang[3], Guihong Tan[1], Raamesh Deshpande[3], Yiqun Chen[1], Matej Usaj[1], Att...
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Director's Report Outline

I. General NHGRI Updates

II. General NIH Updates

III. General Genomics Updates

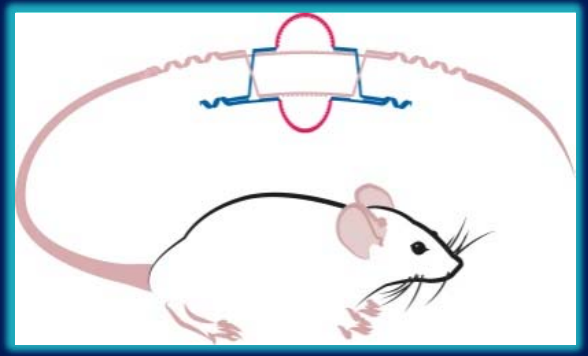
IV. NHGRI Extramural Research Program

V. NIH Common Fund/Trans-NIH

VI. NHGRI Division of Policy, Communications, and Education

VII. NHGRI Intramural Research Program

Knockout Mouse Phenotyping Project (KOMP2)



IMPC
International Mouse Phenotyping Consortium

- KOMP2 Collaboration Meeting – October, 2018
- IMPC - INFRAFRONTIER Meeting – December, 2018

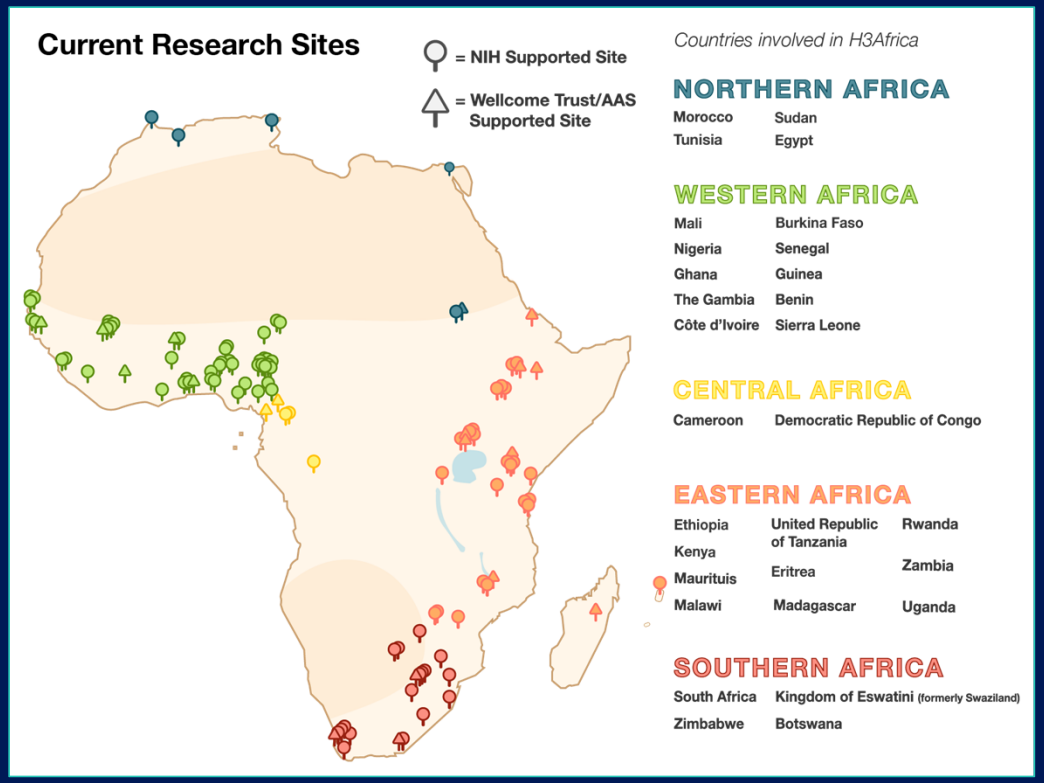
Gabriella Miller Kids First Pediatric Research Program

Gabriella Miller Kids First PEDIATRIC RESEARCH PROGRAM

- **Kids First – KOMP2 Collaboration: Precision Modeling of Pediatric Conditions**
- **Accepting nominations of disease alleles for mouse model production and phenotyping**

Upcoming Due Dates: February 22 and April 5

Human Heredity and Health in Africa (H3Africa)



H3Africa Biorepository Program

CLS CLINICAL LABORATORY SERVICES

IBR H3A U

INSTITUTE OF HUMAN VIROLOGY

H3ABioNet

Pan African Bioinformatics Network for H3Africa

Undiagnosed Diseases Network (UDN)

Effect of Genetic Diagnosis on Patients with Previously Undiagnosed Disease

The NEW ENGLAND JOURNAL of MEDICINE
2018 Nov 29;379(22):2131-2139

- **First 1,519 applicants**
- **35% (132/382) of patients received a diagnosis**
- **31 new syndromes defined**

Undiagnosed Diseases Network
Solving Medical Mysteries Through Team Science

Table 2. Diagnoses According to Method.

Diagnosis	Patients with Complete Evaluation (N=382)
	no./total no. (%)
Diagnosis by any method	132/382 (35)
Clinical review	15/132 (11)
Directed clinical testing	14/132 (11)
Nonsequencing genomewide diagnostic assay	5/132 (4)
Exome or genome sequencing*	98/132 (74)
Reanalysis of previously obtained sequencing data	11/132 (8)
Exome sequencing through the UDN	55/132 (42)
Had previously undergone exome sequencing	6/132 (5)
Genome sequencing through the UDN	32/132 (24)
Had previously undergone exome sequencing	17/132 (13)
No diagnosis	250/382 (65)

* One diagnosis was established by both exome and genome sequencing.

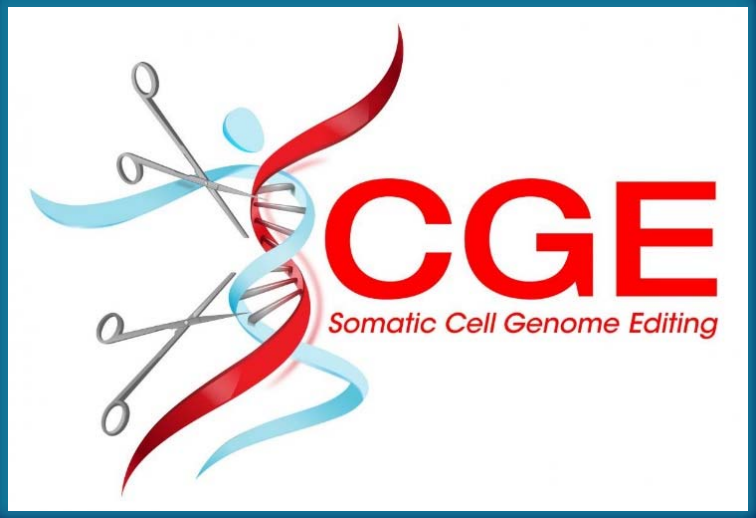
Follow us on social media for real-time research updates at udnconnect and @UDNconnect

Human Biomolecular Atlas Program (HuBMAP)

- New NIH Common Fund program
- First all-hands meeting in November 2018
- RFA-RM-19-002 – Rapid Implementation of Technologies (UG3)

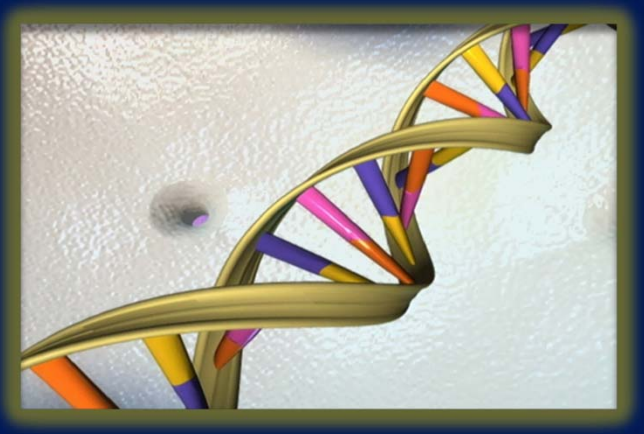
Applications due on March 14

Somatic Cell Genome Editing (SCGE)



- Kickoff meeting held in December 2018
- Data Coordination Center at Medical College of Wisconsin
- Second round applications under review

All of Us
RESEARCH PROGRAM



3 Genome Centers Funded:

- Baylor College of Medicine, with Johns Hopkins University and University of Texas
- Broad Institute, with Color Genomics and Partner's HealthCare
- University of Washington

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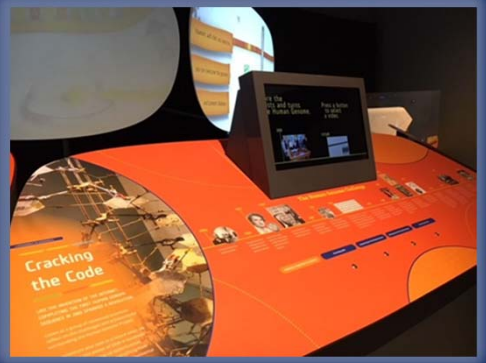
New Video Highlight NHGRI Story

Venditti Video

Genome: Unlocking Life's Code Exhibition
Travel Schedule



GENOME
UNLOCKING
LIFE'S
CODE

- **January 19 – May 19, 2019**

  McWane Science Center, Birmingham, AL

- **Summer 2019**

  DaVinci Science Center, Allentown, PA

NHGRI Outreach Programs

LabX

2019 NBC4 Health and Fitness Expo

National DNA Day 2019

Genomic Education of Healthcare Professionals Workshop

- 25 healthcare providers
- Recommendations for improving genomics education for providers
- Convene a group to address recommendations

My Family Health Portrait

- **Web-based public tool launched in 2004**
- **Moved to Centers for Disease Control and Prevention in September 2018**

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Dan Kastner Honored as Federal Employee of the Year

Dan Kastner, M.D., Ph.D.

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Charles Rotimi Named 2018 Quartz Africa Innovator

Charles Rotimi, Ph.D.

QUARTZ Africa

Bill Gahl Steps Down as NHGRI Clinical Director

Bill Gahl, M.D., Ph.D.

NIH NHGRI

NHGRI Intramural Research Highlights

Genetics in Medicine

A CRISPR focus on attitudes and beliefs toward somatic genome editing from stakeholders within the sickle cell disease community

JCI insight

FGF21 underlies a hormetic response to metabolic stress in methylmalonic acidemia

nature genetics

Whole-genome sequencing of 175 Mongolians uncovers population-specific genetic architecture and gene flow throughout North and East Asia

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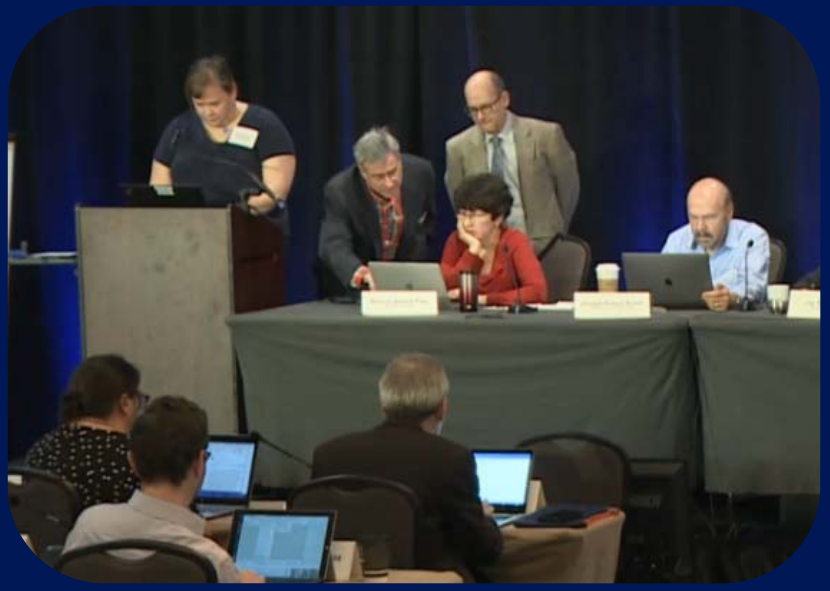
Thanks!



Special Thanks!


The Forefront
of Genomics®