



A Survey of Federal Agency Activities in Genomic Data Sharing

Laura Lyman Rodriguez, Ph.D.
National Institutes of Health
February 4, 2010

SACGHS Interest in Genomic Data Sharing

- Genomic data sharing identified as a priority area through recent priority setting exercise
- Rationale for SACGHS consideration:
 - Potential to facilitate important research
 - May be a key link between research findings & clinical care
 - Raises important ethical questions
 - Challenges paradigm of “de-identifying” data

Goal for Federal Agency Survey

- Why?
 - Government is a major funder of genomics research and is playing an important leadership role
- Goal: To understand the nature and scope of Federal role
 - Gather information about current activities and anticipated developments
 - Identify relevant policies
 - Determine whether there are policy gaps

Survey Questions

- Questions focused on:
 - Existing genomic research programs and any expectations for data sharing
 - The relation of genomic data sharing to agency missions
 - Existence of any policies specific to genomic data sharing
 - Inclusion of elements addressing ethical and legal issues
 - Allowance for research uses and interconnectivity with electronic health records
- Sent to 16 *ex officio* agencies and separately to USDA and NSF

Survey Response



Survey Response – No Activities



U.S. Department of Health and Human Services

Administration for Children & Families

ACF Home | Services | Working with ACF | Policy/Planning |

Survey Response - Mission Relevant



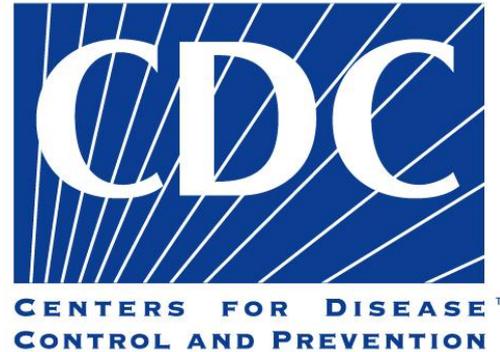
OCR



United States Department of
Health & Human Services

OHRP

Survey Response – GDS Activities



CDC and VA Genomic Data Policies

- NHANES Data Release and Access Policy
http://www.cdc.gov/nchs/data/nhanes/nhanes_release_policy.pdf
- Overview of VA Genomic Medicine Program
<http://www.cdc.gov/genomics/translation/GAPPNet/meeting/file/print/slides/Przygodzki.pdf>

ARTICLE

Genetics IN Medicine • Volume 11, Number 5, May 2009

Veterans' attitudes regarding a database for genomic research

*David Kaufman, PhD¹, Juli Murphy, MS¹, Lori Erby, PhD², Kathy Hudson, PhD¹,
and Joan Scott, MS, CGC¹*

NIH Genomic Data Policies

- Policy for Data Sharing of Genome-Wide Association Studies
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>
- The Cancer Gene Atlas Pilot Project Data Sharing Policy
<http://cancergenome.nih.gov/about/policies/rupdg.asp>
- The Human Microbiome Project Data Release and Resources Sharing Guidelines for Data Production Grants
<http://nihroadmap.nih.gov/hmp/datareleaseguidelines.asp>
- NIDA Roadmap Epigenomics Program Policies
http://www.drugabuse.gov/about/Roadmap/epigenomics/data_access_policies.html
- dbGaP (database of Genotypes and Phenotypes)
<http://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/about.html>

NIH Institute Specific Policies

- NIAAA COGA Genomic Data Sharing Policy
http://www.niaaa.nih.gov/ResearchInformation/ExtramuralResearch/SharedReesources/distribution_agreement.htm
- Genomic Sequencing Centers, NIAID Data & Reagent Sharing and Release Guidelines
<http://www3.niaid.nih.gov/LabsAndResources/resources/gsc/data.ht>
- NIMH National Database for Autism Research Data Sharing Policy
http://ndar.nih.gov/ndarpublicweb/Documents/NDAR_Policy_02152008.pdf
- NHGRI Rapid Data Release Policy
<http://www.genome.gov/10506376>
- ENCODE-modENCODE Data Sharing Policy
<http://www.genome.gov/27528022>
- NHGRI Medical Sequence Data Sharing Policy
<http://www.genome.gov/20019647>

Policies that May Relate to GDS

OHRP

- Guidance on Research Involving Coded Private Information or Biological Specimens

<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.htm>

- Guidance on Engagement of Institutions in Human Subjects Research

<http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html>

- Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards

<http://www.hhs.gov/ohrp/humansubjects/guidance/gina.html>

- Issues to Consider in the Research Use of Stored Data or Tissues

<http://www.hhs.gov/ohrp/humansubjects/guidance/reposit.htm>

EEOC, OCR, OHRP: GINA regulations or guidances

Current GDS Activities - NIH

THE CANCER GENOME ATLAS

The Cancer Genome Atlas (TCGA) Pilot Project

The Human Microbiome Project

Discussion Of Current Status And International Plans To Explore The Human Microbiome

Place:	Metra Toronto Convention Center (South Building), Room 714A, Toronto, Canada
Date:	May 24, 2007
Chair:	George Weinstock, Baylor College of Medicine, Houston, TX
Agenda:	8:00 PM - 7:00 PM Registration 7:00 PM - 7:05 PM Welcome 7:05 PM - 7:05 PM George Weinstock 7:05 PM - 7:05 PM Overview of the National Academy of Sciences report on metagenomics 7:05 PM - 7:45 PM Jo Handelsman, University of Wisconsin, Madison, WI 7:05 PM - 7:45 PM Lessons and challenges for metagenomic studies of the human microbiome 7:45 PM - 8:05 PM David Relman, Stanford University, Palo Alto, CA 7:45 PM - 8:05 PM How will new sequencing technologies enable human microbiome research? 8:05 PM - 8:05 PM George Weinstock 8:05 PM - 8:05 PM The NIH Roadmap human microbiome project briefing report 8:05 PM - 8:05 PM James Peterson, National Human Genome Research Institute, National Institutes of Health, Bethesda, MD 8:05 PM - 8:00 PM Discussion - Q&A

FRAMINGHAM HEART STUDY

Three Generations of Dedication

1948 1971 2002

A Project of the National Heart, Lung, and Blood Institute and Boston University

dbGaP

GENOTYPE and PHENOTYPE

The eMERGE Network

electronic Medical Records & Genomics

A consortium of biorepositories linked to electronic medical records data for conducting genomic studies

NIH Policy Development for Sequence Data

Notice on Development of Data Sharing Policy for Sequence and Related Genomic Data

Notice Number: NOT-HG-10-006

Key Dates

Release Date: October 19, 2009

Issued by

National Human Genome Research Institute (NHGRI), (<http://www.genome.gov/>)

Purpose

The purpose of this Notice is to inform the research community of plans by the National Institutes of Health (NIH) to:

1. Update data sharing policies for NIH supported research, including extramural and intramural projects, involving sequence and related genomic data obtained with advanced sequencing technology (e.g., medical resequencing data, sequence data from non-human species, including microorganisms, transcriptomic and epigenomic data, as well as data needed for interpretation, including associated clinical, other phenotype and metadata, such as supporting study documents and methodologies);
2. Encourage investigators and IRBs to consider the potential for broad sharing of sequence and related genomic data in developing informed consent processes and documents for such studies involving human sequence data; and,
3. Communicate the agency's intent and current underlying considerations related to developing a policy pertaining to the deposition of these large datasets into centralized databases, such as the GenBank Short Read Archive (SRA) or the Database of Genotypes and Phenotypes (dbGaP), so that they are available as broadly and rapidly as possible to a wide range of scientific investigators.

- Extension of the rationale for data sharing policies to date
- Accessibility of whole genome sequencing and other genomic technologies advancing rapidly
- Consistent approach for investigators, institutions secondary users, and participants

Themes

- Genomic data generated from individuals will include sensitive information.
- Broad sharing of genomic data enables and accelerates scientific research
- Policies must ensure privacy and confidentiality of research subjects
- Protection is needed against unauthorized access, distribution or use of genomic data
- Scientific, ethical and societal issues regarding genomic data continue to evolve – data sharing policies must remain relevant and timely

Potential Policy Gaps?

- More guidance/best practices for informed consent
- Additional consideration around data access policies for research participants
- Existing policies do not preclude incorporation into EHRs, but there are not currently structures for inclusion of genomic data

Questions/Future Directions

- Is there a need to develop additional policies relating to genomic data sharing?
 - If yes, should this process be agency-specific or coordinated?
- Is there a need to raise public awareness of the importance of genomic data sharing and the inclusion of such data in the electronic health record?

Acknowledgements

- **SACGHS Staff**
 - Symma Finn
 - Cathy Fomous
 - Sarah Carr
- **SACGHS Ex-officios**