

Clinical Sequencing Exploratory Research (CSER) Steering Committee & Return of Results Consortium

April 30 – May 2, 2012
Bethesda, MD



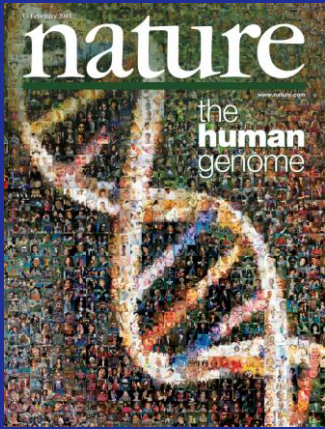
genome.gov

National Human Genome Research Institute

National Institutes of Health

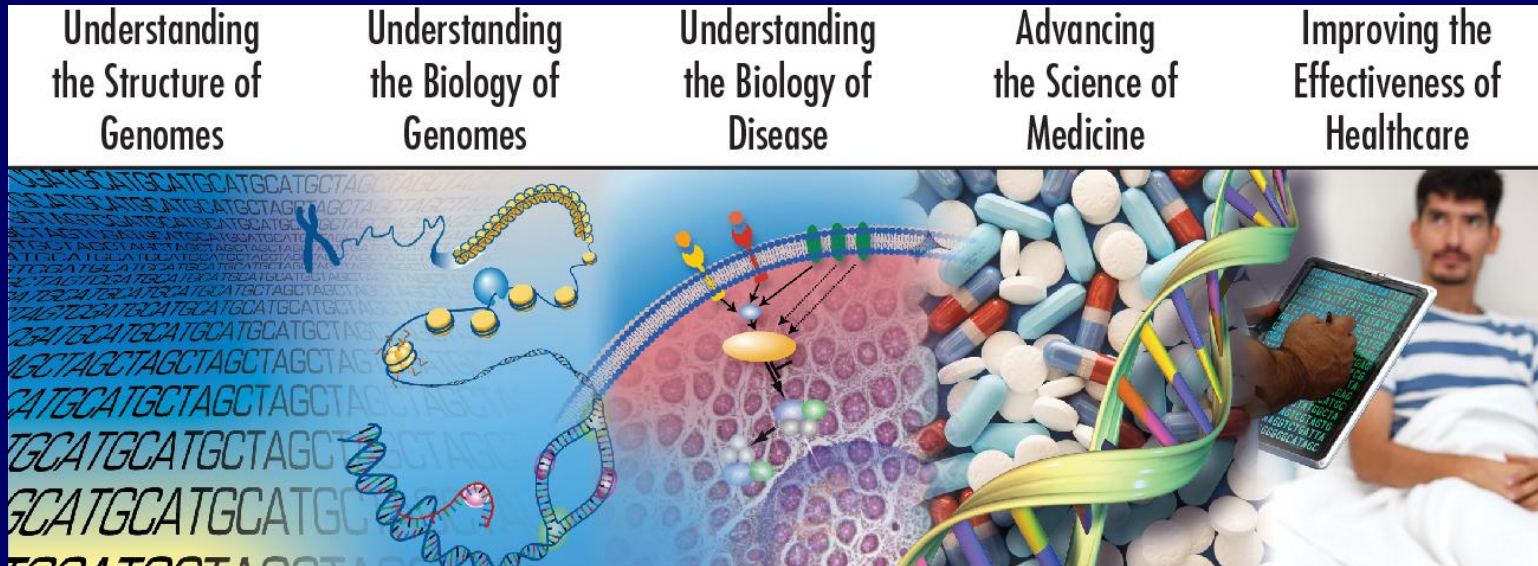


The Path to Genomic Medicine



Human Genome Project

Realization of Genomic Medicine



Funding Opportunities

CSER re-issue

CSER & RoR Coordination Center

Genomic Medicine Demo Projects

Office of the Director supplements

RFA HG 10 -017, HG 12-009

Clinical Sequencing Exploratory Research

- **Research the challenges to applying comprehensive genomic sequence data to the care of patients:**
 - **generation and application of genomic sequence data in the clinical workflow and timeline,**
 - **interpretation and translation of the data for the physician,**
 - **communication to the patient.**
- **Examine the ethical and psychosocial implications of bringing broad genomic data into the clinic.**
- **Variant discovery is secondary to these primary aims.**

RFA 12-008

Goals of CSER Coordination Center

- Facilitate the work of the CSER Consortium through scientific coordination, logistical and administrative activities
- Accelerate the generation and dissemination of findings and best practices
- Support interactions and potential collaborative activities with related efforts, especially RoR Consortium

GENOMIC MEDICINE DEMONSTRATION PROJECTS

Objective: Demonstrate feasibility of, and develop methods for, incorporating patients' genomic findings into their clinical care

Goals:

1. Expand existing GM efforts and develop new projects and methods, in diverse settings
2. Contribute to evidence base regarding outcomes of implementing GM
3. Define and disseminate processes of GM implementation, diffusion, and sustainability in diverse clinical settings

APPROACH

- Link early adopter sites to less experienced groups
- Expand number and types of sites at which implementation being done
 - Health maintenance organizations
 - Community hospitals and private practices
 - Military or veterans' care
 - Underserved and indigent populations
- Develop best practices
- Collect evidence of impact on outcomes

PAS-12-166

Limited Competition: Revision Applications to Advance Evidence-Based Research Related to Protections for Human Subjects (U01)

- **Seeks revision applications to cooperative agreements that are supporting networks or consortia of researchers who conduct or will be interested in conducting research in the following areas:**
 - **The effectiveness of current human subjects protections and the development of tools and methods to examine evolving, evidence-based approaches to improve human subjects protections.**
 - **The feasibility, costs, benefits, and impacts of requiring consent for research on deidentified human specimens and data using novel models of consent, e.g., notification, opt-out, opt-in, broad consent.**

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