

Proposed VA Genomic Medicine Program

- Research & development of clinical programs targeting therapeutic drug response & preventing adverse reactions
 - Lab capability for pharmacogenomic profiling
- Research into role of genetic factors in prevention and causation of disease
- Develop information systems to confidentially manage genetic data for patient care & research

Rationale

- Largest integrated health system in U.S.
- Large, stable patient population
 - 7,291,766 unique enrollees & 4,494,338 users
- Electronic health record
- Integrated research program
- Incipience of genomic medicine
- Altruistic patients

Existing Resources and Proposed Approach

- Several DNA banks in existence
 - Other repositories associated with individual studies
- 3 competing approaches under consideration
 - blood spot cards
 - frozen lymphocytes
 - immortalized lymphocytes
 - combinations

Operating Principles

- VA would maintain absolute control and ownership over biologic materials and clinical/genetic information
- All research would be governed by existing stringent policies related to scientific merit, privacy, human subjects protections, intellectual property, investigator conflict of interest, etc.
- Additional protections afforded by National Oversight Board.

Issues

- Governance
- Protection of confidentiality
- Prevention of exploitation
- Collaborations
- Logistics
 - Patient sample
 - Specimen acquisition: DNA, other specimens
 - Processing & storage
- Demographic and exposure data
- Cost
- Intellectual property