

# National Committee on Vital and Health Statistics

(NCVHS)

## Subcommittee on Privacy and Confidentiality

Salt Lake City, Utah  
November 6, 2002

What areas are especially in need of guidance from OCR? What difficulties are providers and plans experiencing coming into compliance?

# RESOURCE FOR GENETIC & EPIDEMIOLOGIC RESEARCH (RGE)

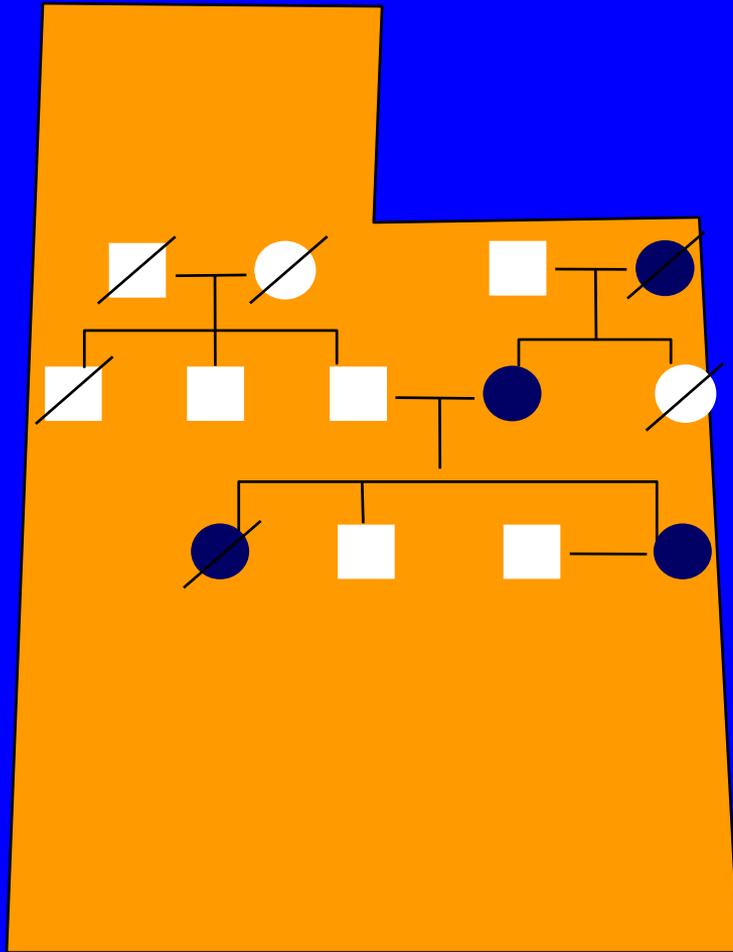
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# RGE

Established by an Executive Order of the Governor in 1982 as “...a data resource for the collection, storage, study and dissemination of medical and related information for the purpose of reducing morbidity and mortality...”

Governs access to the Utah Population Database  
(UPDB)

# Utah Population Database (UPDB)



- University of Utah research resource for biomedical and health related research
- Data sets contain 6.5 million records
- Over 40 approved projects

# Records within UPDB

Type of record	Source of record	Number of records
family history <sup>1</sup>	LDS Church	1.6 million
birth & fetal death	Utah Dept. of Health	1.8 million
death certificates	Utah Dept. of Health	650,000
cancer registry	Utah & Idaho registries	285,000
driver license	Ut. Dept. of Public Safety	2.3 million
HCFA (CMS) follow-up	CMS	139,000

**Data are linked to create a “person record” with associated events, such as cause of death, cancer diagnosis, birth complications, etc.**

1. Contains a subset of records from the Utah Genealogical Society. Records were abstracted for individuals with a life event - birth, death or marriage - on the pioneer trail or in Utah. Thus, they represent the ancestors of many contemporary Utahns.

# Research Using UPDB

- Cancer and Cancer Genetics

Breast, Colorectal, Melanoma, Ovarian, Pancreatic, Prostate  
Statistical analyses of all cancers

- Other Diseases/Conditions

1. Aneurysms

2. Autism

3. Dilated Cardiomyopathy

4. Interstitial Lung Disease

5. Juvenile Rheumatoid Arthritis

6. Mortality/Longevity

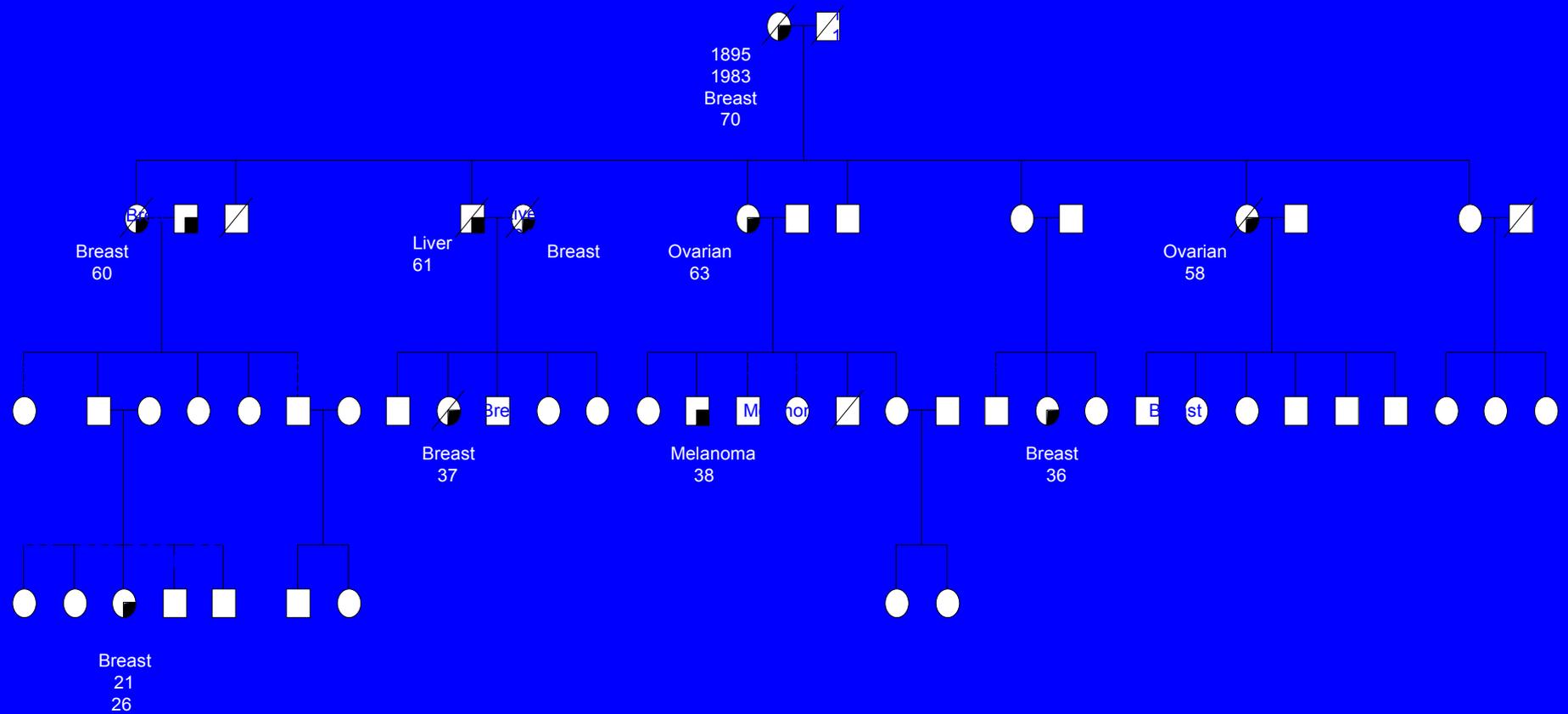
7. Obstetric Complications

8. Psoriasis

9. Rheumatic Fever

10. Type 1 and 2 Diabetes

# High Risk Breast Cancer Family



# Operation of RGE

- Contracts with data contributors
  - specify use conditions
  - require review and approval of use
- Use is project-specific **ONLY**
  - researcher submits application for review by review committee and data contributor(s)
  - project must have IRB approval
  - annual renewal
  - data disposal plan at end of project

# Operation of RGE

- for epidemiology studies, etc., data sets are provided to researcher for analysis
- for contact studies, subjects are contacted by:
  - a third party such as RGE, cancer registry; OR
  - a physician/health care institution that was the source of the records
- individually identifying information is NOT provided to researcher until subject agrees

# UPDB

## **Strengths:**

- Family history data + vital records = ~population of Utah
- Statewide cancer registry = population of Utah
- Great for cancer research

## **Limitations:**

- Health data limited to cancer, vital records
- Researchers must provide cases for other diseases

# University of Utah Health Sciences Center Data Warehouse (DW)

Demographic information for ~ 1.3 million people

Medical/clinical information =

- lab results (general lab, microbiology, and pathology) (from 1993)
- pharmacy data (from 1999)
- ICD9 coded diagnosis and procedure data (from 1993)
- radiology results (from 1993)
- blood gas (from 1995)
- outpatient documentation (clinic notes, medications, problems, allergies) (from 1996)
- UUHN clinic data (Electronic Medical Record) (from 2000)

~ 21% of the Utah health care market

# UPDB + DW =

1. Greatly increased health data
  - kinds of data
  - numbers of people
2. For some disease/conditions represents most, if not all, the population
3. Linking is within one covered entity so no HIPAA issues



21% of the health care market  
 $\neq$   
population



**Need population-level medical data**



**HIPAA**

# UPDB + non-UU health data = HIPAA

- HIPAA: patient consent/authorization required

At a population level, this would:

1. Be prohibitively expensive
2. Result in a non-representative sample

- Waiver of this requirement possible if:

1. IRB/Privacy Board approves; or
2. Researcher is only reviewing records  
“preparatory to research”...

# UPDB:

not a research project

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a data research resource

# HIPAA & Data Research Resources:

- Comments to proposed modifications of privacy rule, April 2002
- Response to comments, August 2002
- OPPR “Issues to Consider in the Research Use of Stored Data or Tissues”, November 1997

# HIPAA & Research Resources: Data-Only

OPPR documents based on:

- tissue repositories
- consented donors
- small samples
- “stand-alone” data/samples

# Questions:

1. Is an IRB/PB waiver of consent for creation of research resources the most appropriate method of managing such resources? What criteria would they use?
2. If IRB/PB waiver not appropriate, may a covered entity release records for such a resource as “preparatory to research”?

# Solutions

1. HIPAA waiver of consent/authorization for data research resources;
2. Disclosing entity maintains record of disclosure;
3. IRB approval of all research using research resources;
4. Institutional oversight of operation of research resources.

# UPDB NOT UNIQUE

*Electronic data linking creates:*

1. Enormous research potential
2. Significant privacy and confidentiality issues