

# Description of the California Research-Ready Biospecimen Bank

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# Timeline of Critical Milestones

- 1980 Newborn Screening Specimen Bank
- 1992 March of Dimes Grant
- 2000 TRDRP Grant: Project Baby's Breath  
Prenatal Screening Specimen Bank
- 2003 CBDMP-funded Prenatal Screening  
Specimen Bank
- 2006 Legislation (SB 1555)
- 2008 Legislation (AB 2599)
- 2009 NIH Grant: CRRBB

# Permitted Research Purposes

1. Identify risk factors for children's and women's diseases
2. Develop and evaluate:
  - screening tests
  - prevention strategies
  - treatments

# Aims of NIH Grant

1. Establish highly efficient protocols, procurement and integration of automated systems for pulling and processing specimens
2. Develop integrated specimen tracking system into existing web-based Screening Information System (SIS)
3. Develop a linked screening program-vital records data base that is organized into a life course, client based system
4. Develop computerized system to track application requests for specimens and data

# Other Biobank Project Aims

- Establish regulations and fees structure to maintain a self-sustaining California Research-Ready Biospecimen Bank (CRRBB)
- Build new storage facility that can provide ready access to specimens
- Acquire or identify new State-funded positions to maintain Life Course data base and request management operations
- Define and implement a plan for maintenance and operations to support software and hardware needs of SIS Biobank in the future

# Resources

## Frozen Specimens

- 15 million newborn screening specimens (5 dried blood spots) + 510,000 annually
- 1 million prenatal screening specimens (2 ml serum, 2 ml cell pellet) + 70,000 annually

## Data (linked at the client level):

- |                                  |                   |       |
|----------------------------------|-------------------|-------|
| • Newborn Screening Program      | 510,000 per year  | 1982+ |
| • Prenatal Screening Program     | 350,000 per year  | 1987+ |
| • GDSP Disorders Registries      | linked to clients | 1982+ |
| • Live Births                    | 510,000 per year  | 1982+ |
| • Fetal Deaths (20+ weeks gest.) | 3,000 per year    | 1982+ |
| • Deaths                         | linked to clients | 1982+ |

# Life Course Data Base

## Record Linkage

- Data Preparation and Cleaning
- Tibco Matching Engine
- Post-Processing Rules
- Clerical Review

## Levels of Analysis

- Specimen
- Pregnancy
- Client (including child, father, mother, pregnancy history)
- Family (including siblings and intergenerational)

# Fees

## Biospecimens

- Newborn Screening Program Dried Blood Spot
  - A/ Pre-identified \$22
  - B/ A & neighbor controls \$18
  - C/ Batched \$16
  
- Prenatal Screening Program Specimens
  - Serum (1 ml vial) \$37
  - Cell Pellet \$37



# Fees

## Data

- GDSP fees for newborn and prenatal screening program data which are linked to biospecimens requested, or screening program data linked to vital records data
  - Fee is based on the sum of the cost of the records provided multiplied by the values of the following four factors:
    - (1) number of years of records
    - (2) number of variables per record
    - (3) number of GDSP registry disorders & data bases utilized
    - (4) type of study population

## Examples

Records	Years	Vars	D.B.	Type	Fee (\$)
400	4	4	2	Pre-identified	2,500
150,000	2	15	1	Random	2,000
35,000	26	40+	2	Pre-identified	160,000

# Fees

## CBDMP Data

➤ Hourly Rate \$62

## Additional Services

➤ Hourly Rate \$62

- IRB protocol development and renewal
- Record linkage when Birth State File Number is unknown
- Data analysis
- Manuscript preparation

# Application Process

## Researcher uses SIS to transmit these items:

- Grant application or detailed research protocol
- Application to and approval letter from California Health and Human Services Agency Committee for the Protection of Human Subjects
- Researcher CV
- Description of the data and biospecimens needed for the research project
  - Name and address to which to send the data and/or biospecimens
  - Description of packing requirements and method of shipment of biospecimens
  - Plan that ensures return of biospecimens to the Department after completion of the research study
- Description of any additional services requested
- Signed Data/Biospecimen Use and Confidentiality Agreement form
- Payment and approval letter from the Office of the State Registrar for requests that include a release of vital records data

# Completion Timeline

- 2011 Specimen and request tracking software
- 2012 Application review procedures  
New freezer for NBS program specimens  
Life course database - 1982-2007  
Regulations  
Biobank Program web-site  
Budget and staff recruitment
- ? Open doors