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

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<th>Vars</th>
<th>D.B.</th>
<th>Type</th>
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<tr>
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<td>26</td>
<td>40+</td>
<td>2</td>
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</table>
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