

State of California
Office of Administrative Law

RECEIVED JAN 22 2015

In re:
Department of Public Health

NOTICE OF FILING AND PRINTING ONLY

Regulatory Action:

Government Code Section 11343.8

Title 17, California Code of Regulations

Adopt sections: 6550, 6551, 6553, 6553.1,
6555, 6557, 6557.1, 6557.2,
6557.3

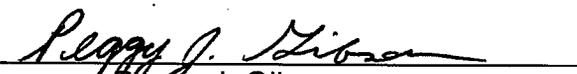
OAL File No. 2014-1224-02 FP

Amend sections:
Repeal sections:

This File/Print action is the "Statement of Compliance" filing making permanent the prior emergency establishing requirements for the Biobank Program. The Biobank maintains a large and diverse biobank of over 17.5 million prenatal and newborn biospecimens, Genetic Disease Screening data and California Birth Defects Monitoring data. It also links these biospecimens and data to the State Registrar of Vital Statistics, databases that include fetal death, live birth and death data. The State of California has mandated that these biospecimens be stored, analyzed and shared for research purposes. The emergency action established guidelines for invoicing, charging and collecting fees as well as specified the protocols and conditions under which requests for research will be approved and released. Additionally, protocols and conditions for biospecimen retrieval, re-inventory and shipping were established. The emergency file was 2014-0515-04EFP.

OAL filed these regulations with the Secretary of State, and will publish the regulations in the California Code of Regulations.

Date: 1/21/2015


Peggy J. Gibson
Senior Attorney

For: DEBRA M. CORNEZ
Director

Original: Dr. Ron Chapman, MD, MPH
Copy: Linda Cortez

FILE PRINT

STATE OF CALIFORNIA—OFFICE OF ADMINISTRATIVE LAW

NOTICE PUBLICATION REGULATIONS SUBMISSION

(See instructions on reverse)

For use by Secretary of State only

STD. 400 (REV. 01-2013)

OAL FILE NUMBERS	NOTICE FILE NUMBER Z-2014-0825-02	REGULATORY ACTION NUMBER 2014-1224-02FP	EMERGENCY NUMBER
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For use by Office of Administrative Law (OAL) only

2014 DEC 24 AM 9:24
OFFICE OF ADMINISTRATIVE LAW

ENDORSED - FILED
in the office of the Secretary of State
of the State of California

JAN 21 2015

2:21 PM

NOTICE

REGULATIONS

AGENCY WITH RULEMAKING AUTHORITY
CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

AGENCY FILE NUMBER (if any)
DPH-09-020E

A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)

1. SUBJECT OF NOTICE		TITLE(S)	FIRST SECTION AFFECTED	2. REQUESTED PUBLICATION DATE	
3. NOTICE TYPE <input type="checkbox"/> Notice re Proposed Regulatory Action <input type="checkbox"/> Other		4. AGENCY CONTACT PERSON		TELEPHONE NUMBER	FAX NUMBER (Optional)
OAL USE ONLY	ACTION ON PROPOSED NOTICE <input type="checkbox"/> Approved as Submitted <input type="checkbox"/> Approved as Modified <input type="checkbox"/> Disapproved/Withdrawn			NOTICE REGISTER NUMBER 2014 362	PUBLICATION DATE 9/5/2014

B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)

1a. SUBJECT OF REGULATION(S) CALIFORNIA BIOBANK PROGRAM	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S) 2014-0515-04 EFP, 2014-0825-02
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2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) (Including title 26, if toxics related)	
SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)	ADOPT 6550, 6551, 6553, 6553.1, 6555, 6557, 6557.1, 6557.2, and 6557.3
	AMEND
TITLE(S) 17	REPEAL

3. TYPE OF FILING			
<input type="checkbox"/> Regular Rulemaking (Gov. Code §11346)	<input type="checkbox"/> Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.	<input type="checkbox"/> Emergency Readopt (Gov. Code, §11346.1(h))	<input type="checkbox"/> Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
<input type="checkbox"/> Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4)	<input type="checkbox"/> Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)	<input checked="" type="checkbox"/> File & Print	<input type="checkbox"/> Print Only
<input type="checkbox"/> Emergency (Gov. Code, §11346.1(b))		<input checked="" type="checkbox"/> Other (Specify) Pursuant to HSC section 124977(d)	

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1)

5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)			
<input type="checkbox"/> Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a))	<input type="checkbox"/> Effective on filing with Secretary of State	<input type="checkbox"/> §100 Changes Without Regulatory Effect	<input checked="" type="checkbox"/> Effective other (Specify) Emergency Regs HSC section 124977(d)

6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY			
<input checked="" type="checkbox"/> Department of Finance (Form STD. 399) (SAM §6660)	<input type="checkbox"/> Fair Political Practices Commission	<input type="checkbox"/> State Fire Marshal	
<input type="checkbox"/> Other (Specify)			

7. CONTACT PERSON LINDA M. CORTEZ	TELEPHONE NUMBER 916-440-7807	FAX NUMBER (Optional) 916-440-5747	E-MAIL ADDRESS (Optional) linda.cortez@cdph.ca.gov
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8. I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

SIGNATURE OF AGENCY HEAD OR DESIGNEE <i>Karin S. Schwartz</i>	DATE 11/25/14
TYPED NAME AND TITLE OF SIGNATORY KARIN S. SCHWARTZ, DEPUTY DIRECTOR AND CHIEF COUNSEL	

For use by Office of Administrative Law (OAL) only

ENDORSED APPROVED

JAN 21 2015

Office of Administrative Law

Statement of Compliance with Health and Safety Code Section 124977

The Department has complied with the provisions of Health and Safety Code section 124977(d)(1) by holding a public hearing on September 17, 2014, within 120 days of filing the emergency regulations with the Secretary of State and has complied with Government Code sections 11346.8 and 11346.9. The emergency regulations were filed with the Secretary of State on May 20, 2014.

**Title 17, California Code of Regulations
Division 1, Chapter 4, Subchapter 9
Group 6. California Biobank Program**

Article 1. Definitions.

Adopt Section 6550 to read as follows:

Section 6550. California Biobank Program Definitions.

For the purposes of this group the following definitions under authority of the California Hereditary Disorders Act (Sections 124975 through 124996 of the California Health and Safety Code (HSC), Newborn Screening (Sections 125000 through 125002 of the HSC), and Prenatal Testing (Sections 125050 through 125119.5 of the HSC) apply.

(a) "Batch" means biospecimens that are located in the same box, bag, bin or other container in the California Biobank Program's storage facilities.

(b) "Biospecimen" means a blood sample collected from a person for the purposes of newborn or prenatal testing and which may be subsequently stored for program development or research purposes.

(c) "California Biobank Program" or "CBP" means the administrative activities performed by the Department in connection with the storage and distribution of biospecimens, including assessment of research requests for biospecimens, and the establishment of fees related to biospecimens.

(d) "California Birth Defects Monitoring Program" or "CBDMP" is part of Maternal Child and Adolescent Health or MCAH and is one of the programs that makes up the CBP and which is administered by the California Department of Public Health.

(e) "Case biospecimen" means one specific biospecimen requested by a researcher that is defined according to criteria provided by the researcher and is from an individual known to have a specific condition.

(f) "Control biospecimen" means one specific biospecimen that is defined by the researcher and is from an individual that is not thought to have a specific condition.

(g) "Department" means the California Department of Public Health, Center for Family Health.

(h) "Genetic Disease Screening Program" or "GDSP" is one of the programs that makes up the CBP and which is administered by the California Department of Public Health.

(i) "Newborn Biospecimen" means a sample of blood that was collected and screened for specific disorders by the Department's Newborn Screening Program and stored by the CBP after testing is completed.

(j) "Newborn Screening Program" or "NBS" means the program within GDSP that screens newborns in California for genetic or congenital disorders. Screening takes place in Department approved screening laboratories.

(k) "Newborn Screening Specimen Collection Filter Paper Card" means the Department filter paper that biospecimens are collected on.

(l) "Prenatal Biospecimen" means a sample of blood collected from a pregnant woman for the Department's Prenatal Screening Program. The biospecimens are screened by the Department and those biospecimens that are stored, are processed and separated into two components, serum aliquot and cell pellet.

(m) "Prenatal Screening Program" or "PNS" means the program within GDSP that screens pregnant women for prenatal birth defects. Screening takes place in Department approved screening laboratories.

(n) "Screening Information System" or "SIS" means the CBP's databases and associated data entry screens. Researchers will be granted access to designated SIS screens that they will use to request biospecimens and/or data and upload research request documents.

Note: Authority cited: Sections 124977, 124991, 125002, 131050, 131051, 131052, and 131200, Health and Safety Code.

References: Sections 124975-124996, 125000, 125001, 125002, and 125050-125119.5, Health and Safety Code.

Article 2. Request Application Process.

Adopt Section 6551 to read as follows:

Section 6551. Application Process for Requests for Biospecimens and/or Data.

This section establishes requirements for the application process that must be followed to obtain biospecimens and/or GDSP data related to the biospecimens, and to obtain live birth, fetal death, and/or death data linked to the biospecimens. This section also establishes requirements for the application process that must be followed to obtain CBDMP data, whether or not it is linked to biospecimens.

(a) The researcher shall convey in writing to staff of GDSP, CBDMP or MCAH the following information:

(1) A request for biospecimens and/or data.

(2) A description of the research project.

(3) The name and title of the researcher and the phone number, email address, and institution name at which the researcher may be contacted.

(b) After receiving the request described in subdivision (a), the Department shall provide to the researcher information and procedures for accessing SIS.

(c) The researcher shall use the SIS system to transmit the following items:

(1) The grant application or a detailed research protocol which describes the specific aims, significance, methods and analyses of the research project.

(2) A copy of the approval letter received from the California Committee for the Protection of Human Subjects (CPHS), including subsequent modifications and renewals if any.

(3) A copy of the application that was transmitted to CPHS to obtain approval for this research request.

(4) A signed data use and confidentiality agreement establishing that the researcher shall comply with all state and federal privacy and confidentiality laws.

(5) A description of the methods that will be followed in order to maintain the confidentiality of the biospecimens and/or data.

(6) The curriculum vitae of the researcher.

(7) A current approval letter from the State Registrar of Vital Statistics for projects that require vital records data as set forth in Sections 102430(a)(4) and 102430(c) of the HSC.

(8) A description of the biospecimens needed for the research project, identifying whether they are Newborn or Prenatal biospecimens and the number of biospecimens required for the research project.

(9) A description of the data needed for the research project

(10) The name and address to which to send the biospecimens and/or data.

(11) A description of the requested packing materials for the biospecimens.

(12) A description of the requested method of shipment of the biospecimens.

(d) Upon completion of the research study, the researcher shall:

(1) Return all unused portions of the biospecimens to the Department after completion of the research study. Biospecimens should be sent via courier service with tracking number and must include a packing list of biospecimen barcodes that are being returned and the total number of biospecimens included in the shipment.

(2) Destroy all data received from the Department after completion of the research study.

(3) Destroy all residual products obtained during the analysis of the biospecimens received from the Department after completion of the research study.

(4) Researchers conducting studies that perform whole genome sequencing or whole exome sequencing shall not link sequence data derived from biospecimens received from the Department to any other databases.

Note: Authority cited: Sections 124977, 124991, 125002, 131050, 131051, 131052, and 131200, Health and Safety Code.

References: Sections 102175, 102465, 124977, 124980, 124991, and 125002, Health and Safety Code.

Article 3. Approval, Denial, and Revocation of Request.

Adopt Section 6553 to read as follows:

Section 6553. Reasons for Denial.

A request shall be approved unless the Department Director or designee determines that any of the following conditions exist:

(a) Researcher did not obtain approval from CPHS for the specific research project submitted, pursuant to Sections 124991(h)(2)(A)-(E) of the HSC.

(b) Research is not in accordance with Section 124991(g)(1-4) of the HSC.

(c) Research hypothesis and/or methods are repetitive of a substantial body of research that is scientifically accepted on the research topic.

(d) There are insufficient Department staffing resources to complete the research request.

(e) Researcher did not return all remaining biospecimens received from the Department to the Department after completion of a previously approved research study.

(f) Researcher did not comply with the Department data use agreement signed by the researcher on a previously approved project(s).

(g) Researcher did not destroy all data received from the Department after completion of a previously approved research study, by a Department approved method for destruction.

(h) Researcher did not destroy all residual products obtained during the analysis of the biospecimens and/or data received from the Department after completion of a previously approved research study, by a Department approved method for destruction.

(i) Researcher did not comply with the Department's requirement that previously approved studies that perform whole genome sequencing or whole exome sequencing shall not link sequence data derived from biospecimens received from the Department to any other databases.

(j) The research request fails to meet the standards, as applied to peer reviewed publications, for experimental design. Reasons for denial of research requests under this subsection shall include but not be limited to:

(1) The study methodology or design would create biased or inaccurate results.

(2) Laboratory tests, data and/or analyses are unlikely to address the scientific aims of the research request.

(3) Study design uses more biospecimens and/or data than are needed to address the scientific aims.

(4) The statistical analysis and/or statistical testing is unlikely to address the scientific aims of the research study.

(k) Biospecimens being requested are necessary for Departmental program operations and research activities.

(l) The research project requires confidential information or other data from the Office of Vital Records, for which approval has not been granted in accordance with Sections 102430(a)(4) and 102430(c) of the HSC.

(m) The research requires release of an excessive number of biospecimens or an excessive amount of each biospecimen such as to preclude other potential research projects.

Note: Authority cited: Sections 124977, 124991, 125002, 131050, 131051, 131052, and 131200, Health and Safety Code.

References: Sections 102465, 124977, 124980, 12499, and 125002, Health and Safety Code.

Adopt Section 6553.1 to read as follows:

Section 6553.1. Revocation of an Approved Research Request.

An approved research request shall be revoked and the researcher must return all biospecimens and/or destroy all data already received under the research request, to the Department if the Department Director or designee determines that any of the following conditions exist:

(a) The researcher fails to obtain CPHS annual renewal for projects including those involving vital statistics data.

(b) The researcher fails to provide payment for requested biospecimens and/or data received from the CBP.

(c) There has been evidence of use of biospecimens and/or data by the researcher in a manner not approved by the Department, or not identified in the Methods and Protocol Sections submitted to and approved by the CPHS, or otherwise prohibited by law.

(d) Researcher failed to comply with the Department data use and confidentiality agreement signed by the researcher on previously approved project(s).

(e) Researcher did not return all remaining biospecimens to the Department after the completion of a previously approved or revoked research study.

(f) Researcher did not destroy all data received from the Department after the completion of a previously approved or revoked research study, by a Department approved method for destruction.

(g) Researcher did not destroy all residual products obtained during the analysis of the biospecimens and/or data received from the Department after the completion of the research study of a previously approved or revoked research study, by a Department approved method for destruction.

(h) Researcher did not comply with the Department's requirement that studies that perform whole genome sequencing or whole exome sequencing shall not link sequence data derived from biospecimens received from the Department to any other databases.

Note: Authority cited: Sections 124977, 124991, 125002, 131050, 131051, 131052, and 131200, Health and Safety Code.

References: Sections 124977, 124980, 124991, and 125002, Health and Safety Code.

Article 4. Requirements for Citations upon Publication of Results.

Adopt Section 6555 to read as follows:

Section 6555. Requirements for Citations upon Publication of Results.

Publication citations shall be documented into the CBP SIS by the researcher whenever research using biospecimens and/or data obtained from the Department results in publication.

All publications shall indicate that biospecimens and/or data were obtained from the Department.

Note: Authority cited: Sections 124977, 124991, 125002, 131050, 131051, 131052, and 131200, Health and Safety Code.

References: Sections 124977, 124980, 124991, and 125002, Health and Safety Code.

Article 5. California Biobank Program Biospecimen and Data Fees.

Adopt Section 6557 to read as follows:

Section 6557. Newborn Biospecimen Fees.

The fees to obtain newborn biospecimens or newborn screening specimen collection filter paper cards shall be as follows:

(a) \$40.00 per biospecimen if the case biospecimens and control biospecimens are individually identified by specific criteria provided by the researcher.

(b) \$30.00 per biospecimen if the case biospecimens are individually identified and at least as many control biospecimens may be accessed in the same location as the identified biospecimen(s).

(c) \$20.00 per biospecimen if none of the requested biospecimens are individually specified and they can be accessed by batch.

(d) \$1.00 per newborn screening specimen collection filter paper card.

Note: Authority cited: Sections 124977, 124991, 125002, 131050, 131051, 131052, and 131200, Health and Safety Code.

References: Sections 124977, 124980, 124991 and 125002, Health and Safety Code.

Adopt Section 6557.1 to read as follows:

Section 6557.1. Prenatal Biospecimen Fees.

The fee for prenatal biospecimens shall be \$50.00 per biospecimen serum aliquot and \$50.00 per biospecimen cell pellet.

Note: Authority cited: Sections 124977, 124991, 125002, 131050, 131051, 131052, and 131200, Health and Safety Code.

References: Sections 124977, 124980, 124991, and 125002, Health and Safety Code.

Adopt Section 6557.2 to read as follows:

Section 6557.2. Fees Charged by the Department for GDSP Data Provided to Researchers.

A fee of \$265.00 shall be charged by the Department per hour of staff time needed to provide GDSP data that is collected in the administration of the GDSP program.

Note: Authority cited: Sections 124977, 124991, 125002, 131050, 131051, 131052, and 131200, Health and Safety Code.

References: Sections 124977, 124980, 124991, and 125002, Health and Safety Code.

Adopt Section 6557.3 to read as follows:

Section 6557.3. CBDMP Data Fees.

A fee of \$115.00 shall be charged by the Department per hour of staff time needed to provide CBDMP data that is collected in the administration of the CBDMP program.

Note: Authority cited: Sections 124977, 124991, 125002, 131050, 131051, 131052, and 131200, Health and Safety Code.

References: Sections 124977, 124980, 124991, and 125002, Health and Safety Code.