

Newborn Screening Program Resource Manual

Administrative Information and Protocols

January 10, 2012



**California Department of Public Health
Genetic Disease Screening Program**

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Section 1. Confidentiality and Privacy Information

1.1. Employee and Vendor Responsibility

Policy and General Information:

All employees and vendors of the Newborn Screening Program (NBSP) in the Genetic Disease Screening Program (GDSP) will adhere to the California Civil Code Division 3, Part 4, Title 1.8, Chapter 1 The Information Practices Act of 1977 (Civil Code Section 1798 et seq.), which states in part:

“The Legislature declares that the right to privacy is a personal and fundamental right protected by Section 1 of Article I of the Constitution of California and by the United States Constitution and that all individuals have a right to privacy in information pertaining to them.” (Article 6, Section 1798.1)

Article 6, Section 1798.24 of the Information Practice Act describes the circumstances under which disclosures of personal information are allowed.

“The term ‘personal information’ means any information that is maintained by an agency that identifies or describes an individual including, but not limited to, his or her name, Social Security Number, physical description, home address, home telephone number, education, financial matters, and medical or employment history....” (Article 2, Section 1798.3)

All employees and vendors of the NBSP shall adhere to California Statutes of 1995, Chapter 415, Health and Safety Code, Division 104, Part 5, Chapter 1, Article 1, Section 124975(j) which states:

“All testing results and personal information from hereditary disorders programs obtained from any individual, or from specimens from any individual, be held confidential and be considered a confidential medical record except for such information as the individual, parent, or guardian consents to be released; provided that the individual is first fully informed of the scope of the information requested to be released, of all of the risks, benefits, and purposes for the release and of the identity of those to whom the information will be released or made available, except for statistical data compiled without reference to the identity of any individual and except for research purposes....”

All employees and vendors shall adhere to Newborn Screening Regulations (Section 6502.1 Confidentiality) and to confidentiality protocols.

All employees and staff employed by vendors for the NBSP will sign and adhere to a Security and Confidentiality Acknowledgement form (1.1.1.) prior to working with the Program.

Any time that forms (TRF, Result Mailers, etc.) are presented as examples for any purpose, to GDSP or outside staff (where the identifying information is not critical to the work or the situation), names, addresses, ZIP codes, and other identifying information shall be **clearly fictitious** (e.g., Mary Fictitious, No Where Street, CA 99999) or actual patient data shall be "blacked out" or removed. **Actual patient names, addresses and other identifying information shall never be used or be visible.**

The following Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements and principles will be followed:

- When information is requested by any entity not using the information for treatment, payment, and/or health care operations, the minimum necessary information will be communicated from GDSP or Area Service Center (ASC) staff.
- The staff person handling the request for information will verify the requestor's identity and right to the information requested prior to communicating any information that is considered to be Protected Health Information (PHI). PHI is defined as "individually identifiable health information."

In the event of a breach of confidentiality, ASC staff will complete the Breach Incident Reporting Form (1.1.2.) and send to the GDSP Newborn Screening Program (NBSP) Nurse Consultant III/ASC Vendor Liaison.

Associated Forms and Documents:

The forms and documents listed below are provided in the Appendix. If a hyperlink is shown, the form or document can also be found on the Web.

1.1.1. Security and Confidentiality Acknowledgement (CDPH 2420 1/11)

<http://www.cdph.ca.gov/search/results.aspx?k=cdph%20form%202420>

Click on "Security and Confidentiality Acknowledgement"

1.1.2. Breach Incident Reporting Form (CDPH 2375 11/07)

<http://www.cdph.ca.gov/search/results.aspx?k=cdph%20form%202375>

Click on “CDPH Breach/Incident Reporting Form”

Protocol:

N/A

1.2. Fax & E-Mail Communication of Newborn Screening and Phe Monitoring Results

Policy and General Information:

Newborn Screening test, Phe Monitoring results, and other protected health information may be faxed and/or e-mailed to the ASC, California Children's Services (CCS)-Approved Specialty Centers, and other health care providers utilizing the following guidelines to protect privacy and ensure patient confidentiality:

FAX

Fax numbers must be double-checked and confirmed with the intended recipient, and security of the information being faxed will be discussed with the recipient prior to sending to destination.

The following confidentiality statement must be placed on the fax cover sheet:

“NOTE: This fax and any files transmitted with it are confidential and are intended solely for the use of the individual or entity to whom they are addressed. This communication may contain confidential material protected by the physician-patient privilege. If you are not the intended recipient or the person responsible for delivering the fax to the intended recipient, be advised that you have received the fax in error and that any unauthorized use, dissemination, forwarding, printing, or copying of the fax is strictly prohibited by state and federal laws. If you have received this fax in error, please immediately notify sender by fax.”

E-MAIL

Results sent by e-mail will be encrypted whenever possible. From GDSP offices, e-mails can be encrypted by using “[secure]” in the subject line. ASC staff shall use their facility's secure and/or encrypted e-mail systems when sending confidential information.

- All “TO:” and “CC:” fields must be double-checked before sending to destination.
- The following confidentiality statement must be placed in each e-mail:

“This e-mail and any files transmitted with it are confidential and are intended solely for the use of the individual or entity to whom they are addressed. This communication may contain confidential material protected by the physician-patient privilege. If you are not the intended recipient or the person

responsible for delivering the e-mail to the intended recipient, be advised that you have received the e-mail in error and that any unauthorized use, dissemination, forwarding, printing, or copying of the e-mail is strictly prohibited by state and federal laws. If you have received this e-mail in error, please immediately notify sender by reply e-mail.”

- An electronic or hard copy of the e-mail will be retained, per the NBSP retention policy.

Associated Forms and Documents:

None

Protocol:

N/A

1.3. Release of Newborn Screening Results

Policy and General Information:

As specified in the follow-up protocols for each disorder, ASC staff may verbally release Newborn Screening (NBS) results to birth hospitals and physicians for purposes of NBS follow-up. In addition, NBS ASC Coordinators or designees may release results to birth hospitals and physicians providing pediatric care to the child as long as the results are accessible to them in SIS. All other requests must be forwarded to GDSP, per the protocol below.

Results of tests (positive and negative) will be given by GDSP and ASC staff, using the requirements in the protocol below. State-generated forms and letters, or forms containing the same elements as state-generated forms, shall be used for processing requests (1.3.1.).

GDSP and ASC staff must verify the caller/requestor of NBS results. (See specific requirements of verification in protocol below.) Interpreters must be obtained, as needed, for those situations where a language barrier exists.

When faxing results, GDSP and ASC staff must send to a fax that is confirmed to be secure or ask the requestor for a secure fax number. (See 1.2. Policy and General Information.)

Whenever results are released, as outlined in the protocol below, they shall be accompanied by a cover letter describing the difference between screening and diagnosis (1.3.2.).

Microfiche or duplicate copies of NBS Results Mailers from March 1982 to July 11, 2005, are maintained by GDSP and can be accessed through the Newborn Screening Program by contacting the appropriate NBSP staff.

NOTE: Prior to May 10, 1999, NBS Result Mailers (with the exception of the PKU screen) did not report specific values but were reported only as “positive” or “negative.” If actual results/values are needed, they can be obtained through the Newborn Screening Program by contacting the NBSP Nurse Consultant III /ASC Vendor Agreement Liaison.

Associated Forms and Documents:

The forms and documents listed below are provided in the Appendix. If a hyperlink is shown, the form or document can also be found on the Web.

1.3.1. Consent for Disclosure and/or Release of Confidential Information from GDSP

<http://cdphinternet/programs/nbs/Documents/NBS-ConsentReleaseFrmFillable111811.pdf>

1.3.2. Cover Letter for Release of Results

Protocol:

REQUEST BY	FORMS/INFO REQUIRED	RESPONSIBLE PERSON	ACTION/TIMEFRAME
<p>PARENTS</p>	<ul style="list-style-type: none"> • Listed as parent on NBS Record <u>AND</u> • Verification of parentage <u>OR</u> • <u>Signed and Notarized</u> Consent for Disclosure or Release of Confidential Information from GDSP (1.3.1.) <u>OR</u> • <u>Signed</u> Consent for Disclosure or Release of Confidential Information from GDSP (1.3.1.) <u>and</u> copy of government-issued identification (e.g., driver's license, passport, CA State ID Card) • If unable to verify parentage or unable to obtain appropriate documentation, parent should be referred to physician of record for results 	<p>NBS Clinical Services Branch Health Record Tech/Staff <u>OR</u> ASC Project Director or Designee</p>	<ul style="list-style-type: none"> • Verifies parentage by requesting all of and receiving answers to the following information: <ol style="list-style-type: none"> a) Date of Birth b) Hospital of Birth c) Mother's Name/Maiden Name d) Parent/Mother's Address at Time of Birth • If unable to verify parentage, requests <u>signed and notarized</u> Consent for Disclosure or Release of Confidential Information from GDSP (1.3.1.) or <u>signed</u> Consent for Disclosure or Release of Confidential Information from GDSP <u>and</u> copy of driver's license, passport, or CA State ID Card. • Reviews documents for completeness when received. • Releases results via phone, mail, e-mail, or secure fax, per request. Accompanies result with cover letter per Release of NBS Results Policy (1.3.). Documents phone request and release of results by entering appropriate information into SIS Case Notes. • Retains and files written request documents. <u>OR</u> <p>If unable to verify parentage with adequate documentation, refers to physician of record and verifies physician of record. If different physician than NBS Test Request Form (TRF), verifies that physician is in NBS database. If not in database, asks parent to have physician call for result or fax request for result on physician's letterhead.</p>

REQUEST BY	FORMS/INFO REQUIRED	RESPONSIBLE PERSON	ACTION/TIMEFRAME
<p>PRIMARY CARE PROVIDER NOT LISTED IN SIS (For purposes of diagnosis and treatment of child)</p>	<ul style="list-style-type: none"> • No GDSP Consent for Disclosure or Release form required • If not physician of record, need copy of office Consent to Treat form 	<p>NBS Clinical Services Branch Health Record Tech/Staff <u>OR</u> ASC Staff</p>	<ul style="list-style-type: none"> • Verifies that requesting physician is listed as M.D. of record on baby's TRF. If not M.D. of record, asks office to fax copy of Consent to Treat. • Requests enough identifying information to identify and match baby's record in SIS. • Releases results via phone, mail, e-mail, or secure fax. Accompanies result with cover letter per Release of NBS Results Policy (1.3.). • Documents phone request and release of results. Retains and files written request documents.
<p>PHYSICIAN, CCS-APPROVED SPECIAL CARE CENTER (Request for NBS result for sibling of child being treated)</p>	<ul style="list-style-type: none"> • Consent for Disclosure and/or Release of Confidential Information from GDSP (1.3.1) signed by parent 	<p>NBS Clinical Services Branch Health Record Tech/Staff <u>OR</u> ASC Staff</p>	<ul style="list-style-type: none"> • Verifies that requesting physician is listed as M.D. of record. If not M.D. of record, asks office to fax copy of Consent to Treat. • Reviews documents for completeness. • Releases results via phone, mail, e-mail, or secure fax, per request. Accompanies result with cover letter per Release of NBS Results Policy. • Documents phone request and release of results by entering appropriate information into SIS Case Notes. • Retains and files written request and consent documents.

Section 1
Confidentiality and Privacy Information

Effective Date: May 1, 2004
 (Compiled/Modified from Previous Documents)
 Last Revision Date: January 10, 2012

REQUEST BY	FORMS/INFO REQUIRED	RESPONSIBLE PERSON	ACTION/TIMEFRAME
EMERGENCY REQUEST BY PHYSICIAN, CCS-APPROVED SPECIAL CARE CENTER OR HOSPITAL TREATING SICK CHILD	<ul style="list-style-type: none"> No GDSP Consent form required Hospital/Emergency Department Consent to Treat/Conditions of Admission to be obtained and filed with record of request and release of results 	NBS Clinical Services Branch Nurse Consultant III/Staff <u>OR</u> ASC Staff	<ul style="list-style-type: none"> Verifies caller by requesting name of hospital and Emergency Department phone number and calling back. Documents phone request and release of results by entering appropriate information into SIS Case Notes. Releases results via phone or secure fax, per request. Accompanies result with cover letter per Release of NBS Results Policy (1.3.). Requests caller to fax copy of Consent to Treat/Conditions of Admission and retains. (Depending on situation, may require prior to releasing results or may obtain after results are released.) Retains and files written request and consent documents.
LEGAL GUARDIANS OR ADOPTING PARENTS	<ul style="list-style-type: none"> Proof of guardianship or adoption (e.g., birth certificate or adoption papers) <u>AND</u> <u>Signed and Notarized</u> Consent for Disclosure or Release of Confidential Information from GDSP (1.3.1.) from adoptive parent or legal guardian <u>OR</u> Signed GDSP Consent Copy of government-issued ID (e.g., driver's license, passport, CA State ID card) <u>OR</u> If unable to verify, refer back to adoption agency, county of record, or physician of record 	NBS Clinical Services Branch Health Record Tech/Staff	<ul style="list-style-type: none"> Reviews documents for completeness. Releases results via phone, mail, or secure fax, per request. Accompanies result with cover letter per Release of NBS Results Policy (1.3.). Retains and files written request documents. <u>OR</u> If unable to verify parentage with adequate documentation, refers back to adoption agency, county of record, or physician of record (verifies physician of record). If different physician than NBS TRF, verifies that physician is in NBS database. If not in database, asks parent to have physician call for result or fax request for result on physician's letterhead.

REQUEST BY	FORMS/INFO REQUIRED	RESPONSIBLE PERSON	ACTION/TIMEFRAME
ADOPTION AGENCIES	<ul style="list-style-type: none"> • Signed and Notarized Consent for Disclosure or Release of Confidential Information from GDSP (1.3.1.) from Parent or Legal Guardian <p style="text-align: center;"><u>OR</u></p> <ul style="list-style-type: none"> • Valid consent from agency with same information 	NBS Clinical Services Branch Health Record Tech	<ul style="list-style-type: none"> • Reviews documentation for completeness. • Releases results via phone, mail, e-mail, or secure fax, per request. Accompanies result with cover letter per Release of NBS Results Policy (1.3.). • Documents phone request and release of result in SIS Case Notes.
ANY ATTORNEY, SUBPOENA, COURT ORDER, OR OTHER LEGAL ACTION	<ul style="list-style-type: none"> • Signed and Notarized Consent for Disclosure and/or Release of Confidential Information from GDSP (1.3.1.) or other valid consent with the same information signed by parent. <p style="text-align: center;"><u>OR</u></p> <ul style="list-style-type: none"> • Documented subpoena or court order <p style="text-align: center;"><u>AND</u></p> <p>Consent for Disclosure and/or Release of Confidential Information from GDSP (1.3.1.) or other valid consent with the same information</p>	NBSP Nurse Consultant III/ ASC Vendor Agreement Liaison	<ul style="list-style-type: none"> • Reviews documents for completeness; if no Consent for Disclosure, returns documents and requests signed Consent. • Reviews request and completed documents with Chief, NBS Clinical Services Branch; reviews request and completed documentation with Chief, GDSP (or designee), and obtains approval for release. • Finds results and completes letters/forms to transmit information to requestor. • Releases information to requestor. (Accompanies result with cover letter per Release of NBS Results Policy 1.3.) <u>or forwards to State attorney, if appropriate.</u> • Documents request and release of results by entering appropriate information into SIS Case Notes. • Retains and files written request documents. • Maintains log of subpoenas and court orders received, along with documentation of processing and resolution.

Section 1
Confidentiality and Privacy Information

Effective Date: May 1, 2004
 (Compiled/Modified from Previous Documents)
 Last Revision Date: January 10, 2012

REQUEST BY	FORMS/INFO REQUIRED	RESPONSIBLE PERSON	ACTION/TIMEFRAME
CORONER	<ul style="list-style-type: none"> No GDSP Consent form required. 	NBSP Nurse Consultant III/ASC Vendor Agreement Liaison <u>OR</u> Chief, Clinical Services Branch	<ul style="list-style-type: none"> Reviews documents for completeness. Sends results via e-mail or secure fax, per request. Documents phone request and release of results by entering appropriate information into SIS Case Notes. Retains and files written request documents.
HOSPITAL MEDICAL RECORDS/ INFORMATION MANAGEMENT DEPARTMENT <i>(Request from receiving hospital if child has been transferred from birth hospital and screen was performed at birth hospital)</i>	<ul style="list-style-type: none"> Copy of signed Conditions of Admission/ Consent for Treatment or copy of face sheet showing transfer of child from birth hospital. (No consent required if requesting hospital is currently caring for child, there is notation in SIS regarding transfer, and results are in SIS) 	NBS Clinical Services Branch Health Record Tech/Staff	<ul style="list-style-type: none"> Reviews documents for completeness, if necessary. Releases results via phone, mail, e-mail, or secure fax, per request. Documents phone request and release of results by entering appropriate information into SIS Case Notes. Retains and files written <i>request</i> documents.
OTHER REQUESTS: e.g., INSURANCE COMPANIES OR SOCIAL SECURITY	Signed GDSP Consent form (1.3.1.) from client/adult individual, parent, or legal guardian	NBS Clinical Services Branch Health Record Tech/Staff	<ul style="list-style-type: none"> Reviews documents for completeness. Releases results via phone, mail, e-mail, or fax, per request, Accompanies result with cover letter per Release of NBS Results Policy (1.3.). Documents phone request and release of results by entering appropriate information into SIS Case Notes. Retains and files written request documents.

REQUEST BY	FORMS/INFO REQUIRED	RESPONSIBLE PERSON	ACTION/TIMEFRAME
CLIENT/ADULT INDIVIDUAL REQUESTING OWN RESULTS	Signed GDSP Consent form (1.3.1.) from client/adult individual or from parent, if requestor is under the age of 18 OR SIGNED LETTER REQUESTING RESULTS <u>either</u> notarized or sent with copy of driver's license/CA State ID card	NBS Clinical Services Branch Health Record Tech/Staff	<ul style="list-style-type: none"> • Reviews documents for completeness. • Releases results via phone, mail, e-mail, or fax, per request. Accompanies result with cover letter per Release of NBS Results Policy (1.3.). • Documents phone request and release of results by entering appropriate information into SIS Case Notes. • Retains and files written request documents.
STATE NBS PROGRAM FROM ANOTHER STATE	E-mail or written request/fax from program staff with all child's pertinent information.	NBSP Nurse Consultant III	<ul style="list-style-type: none"> • Reviews fax/letter for complete information and searches SIS for results. • Releases results via phone, mail, e-mail, or fax, per request. • Retains and files written request documents.

1.4. NBS Dried Blood Spots (DBS) and Identifying Information—Research Use or Restricting Use and Disclosure

General Information:

1. This protocol includes handling requests for
 - Release of DBS for additional testing
 - Destruction of DBS
 - Return of DBS to parent
 - Family non-contact
 - Removal of identifiers from the NBS record
 - Prohibiting use of DBS for research
 - Prohibiting use of patient Protected Health Information (PHI) for research
 - Request for use of DBS in research
2. All newborn screening blood spots since 1982 are stored by the Genetic Disease Laboratory and can be identified and destroyed at the patient's request.

Policy:

1. Requests for obtaining the DBS for additional testing shall be made to the Chief, Genetic Disease Screening Program (GDSP) by using the Consent for Disclosure and/or Release of Dried Blood Spots from GDSP (1.4.1.) or by sending a letter including the same information as in the form.
2. Requests for restricting use and disclosure of NBS Dried Blood Spots and identifying information and destruction or return of specimens must be in writing and sent to the Chief, GDSP in Richmond, CA. The written request may be made by using the form Request to Restrict Use and Disclosure of Personal Information by Parent, Guardian or Personal Representative (1.4.2.) or by letter. When requests are made by letter, the letter must include the following identifying and request information:
 - baby's name
 - baby's date of birth
 - baby's hospital of birth

- first and last name of baby’s mother
 - Specific information about request, e.g., destroy specimen, return specimen (include where specimen is to be returned), de-identify specimen, etc.
3. Requests for use of DBS in research should be directed to Marty Kharrazi, Ph.D., Research Scientist Supervisor by phone (510-412-1480), e-mail (Marty.Kharrazi@cdph.ca.gov), or written request to 850 Marina Bay Pkwy, F-175, Richmond, CA 94804. Information should include DBS requested, the intended use of the DBS, name of primary researcher, and contact information.

Associated Forms and Documents:

The forms and documents listed below are provided in the Appendix. If a hyperlink is shown, the form or document can also be found on the Web.

- 1.4.1. Consent for Disclosure and/or Release of Dried Blood Spots from GDSP
- 1.4.2. Request to Restrict Use and Disclosure of Personal Information by Parent, Guardian or Personal Representative (CDPH Form 6241 (4/09)
<http://www.cdph.ca.gov/pubsforms/forms/Pages/Privacy-HIPAA-Office.aspx>

Click link above, and then click “CDPH 6241”

Protocol:

Resp. Person	Action
Requestor	<ul style="list-style-type: none"> • Sends written request, including all pertinent information to Chief of GDSP (See Policy #1 & #2 above) or to Research Scientist Supervisor. (See Policy #3 above.)
Chief, GDSP	<ul style="list-style-type: none"> • Forwards written request for release of DBS for additional testing to GDSP Assistant Chief, Administrative Support. • Forwards written request for all other restrictions of use of DBS and identifying information to designated Program Development and Evaluation Branch (PDEB) research scientist to process.
GDSP Assistant Chief, Administrative Support OR Research Scientist Supervisor	<ul style="list-style-type: none"> • Processes request.

Section 2. Administrative Scope of Work Information and Requirements

2.1. Retention and Disposal of Area Service Center Newborn Screening Program Records and Documents

Policy and General Information:

To provide direction to the ASC staff for retention and disposal of State NBS records, follow-up documentation, and management/administrative records.

- All records maintained by the ASC relating to newborn screening are the property of the State of California and will be retained and/or destroyed in compliance with the Department of Public Health Genetic Disease Screening Program Record Retention Schedule.
- All ASCs will adhere to the following guidelines for retention and disposal of records related to newborn screening. Any questions about the schedule and this policy or protocol shall be addressed to the NBSP Nurse Consultant III/ASC Vendor Agreement Liaison.
- Records shall be retained and maintained at the vendor's site for the designated time(s) noted below. If records are to be moved from the ASC offices to an offsite location, the NBSP Nurse Consultant III/ASC Vendor Agreement Liaison shall be consulted to approve the move.
- Paper records may be scanned and retained in electronic form, if desired, as long as they can be retrieved if necessary. Paper records that have been scanned may then be destroyed.
- Destruction and/or disposal of records beyond the retention date will be accomplished according to state requirements, as mandated by the California Records Management Department. Records beyond the retention date can be purged and destroyed utilizing the ASC's institutional confidential destruction policies and procedures after the NBSP Nurse Consultant III/ASC Vendor Agreement Liaison and the Chief, Newborn Screening Clinical Services Branch (or designee), have reviewed and approved the institution's policies, procedures, and processes.
- NBS records utilized by other agencies/entities (e.g., county birth registrars, public health departments, etc.) should be retained according to their own agency policies and protocols.

- SIS shall be utilized for all documentation of screening follow-up and case activities, using Tracking Events and Case Notes in accordance with NBSP SIS protocol(s) and manuals.

Retention of Records Prior to SIS (MARCH 1982–JULY 11, 2005)

NBS Result Mailers are available on microfiche. Prior to May 10, 1999, Result Mailers (with the exception of PKU screen) did not report specific values, but were reported only as “positive” or negative.” If actual results/values are needed, they can be obtained from the NBSP Health Record Tech or NBSP Nurse Consultant III/ASC Vendor Agreement Liaison, who will consult with staff in the Program Development and Evaluation Branch (PDEB) to determine how to obtain this information.

ASC newborn screening records generated before SIS implementation (July 11, 2005) shall be kept until the child is 7 years of age, and then they can be destroyed/shredded.

Rationale for 7-Year Retention

If a disorder is undetected by NBS, it will most likely be identified and/or diagnosed by the time a child reaches school age.

After Implementation of SIS/Records in SIS

After the implementation of SIS (July 12, 2005—present), retention of a hard copy of any record that is contained in SIS is not required but may be kept at the discretion of the ASC.

Current Rules for Retention of SIS Records: All SIS records are kept in perpetuity; some records are active” (can be accessed by all SIS users based on their security clearance), and some are “archived” (can be accessed only by designated PDEB and/or Information Technology/Deloitte staff, if needed).

“**ACTIVE**” records include newborns who have been positively diagnosed with a disorder **and** those records that have been generated within the last 3 years (based on Accession Date).

“**ARCHIVED**” records are those that were generated more than 3 years ago (based on Accession Date). **NOTE:** If an ASC has a need to access archived records, the ASC shall contact the NBSP Nurse Consultant III/ASC Vendor Agreement Liaison.

Guidelines

1. Management/Administrative records and contracts/vendor agreements:
 - a. GDSP NBS contracts/vendor agreements: Retain for **three (3) years** from the date of the last invoice of the contract/vendor agreement cycle.
 - b. Hard copies of SIS Headline Cases: Retain only for as long as they are used by the ASC for tracking (a few weeks).
 - c. Business Objects/Hospital Evaluation Performance Profile (HEPP) Reports: Retain only as long as they are useful in monitoring and correcting hospital performance.
 - d. Hospital files and records, corrective action plans/quality improvement (QI) plans: Retain for **three (3) years** from the date of the last invoice of the contract/vendor agreement cycle.
 - e. Any documents, letters, newsletters, guidelines, etc. generated by the ASC and approved by the GDSP/NBS Clinical Services Branch shall be retained for three (3) years. If there is deviation from policy or standard documentation, the ASC will keep a copy of the unique letter or document in the infant's record.

Policies/protocols developed by GDSP will be retained by GDSP/NBSP.

2. Hard copies of the newborn screening infant records maintained by the ASC shall include all information that is not kept or documented in SIS (e.g., lab results, follow-up letters, CCS Expedited Service Requests, etc.).
 - a. INITIAL POSITIVES RESOLVED AS NEGATIVE: Retain for **three (3) years** from confirmatory test date.
 - b. POSITIVES RESOLVED AS CASES: Retain all records and related documentation for **seven (7) years** from resolution of case.
 - c. EARLY COLLECTIONS: IF EARLY SPECIMEN COMES BACK NEGATIVE, no need to retain.
 - For early collections that are resolved as documentation errors, retain faxes and other documentation that communicate corrections or verification of demographic data on the TRF for **one (1) year** from the date of the test result. This information and the name of the person from whom the information was obtained should also be documented in SIS Case Notes.

- For specimens deemed to be “True” early collections, where a second specimen is obtained:
 - IF THE SECOND SPECIMEN IS NEGATIVE, no need to retain.
 - IF THE SECOND SPECIMEN IS POSITIVE, handle retention consistent with #2b above. All information and the name of the person from whom the information is obtained should also be documented in SIS Case Notes.
- d. INADEQUATES OR “NOT OBTAINED”
 - IF MATCHED WITH NEGATIVE RESULTS, no need to retain.
 - IF MATCHED WITH POSITIVE RESULTS, handle retention consistent with #2a and #2b above.
 - IF NOT RETESTED FOR ANY REASON (lost to follow-up, refusal, etc.), retain for **three (3) years** past final disposition/documentation date.
- e. NBS-NOs
 - IF AN NBS-NO IS TRANSFERRED TO ANOTHER ASC PRIOR TO RESOLUTION, copies of all documents relating to the infant should be transferred to the receiving ASC to be retained with the record until resolution. Documentation/log entry or other record shall be kept by the transferring ASC to indicate that transfer of the record occurred.
 - NBS-NO WHEN BABY EXPIRED PRIOR TO SPECIMEN COLLECTION: No need to retain if entry has been made in SIS about baby’s death. (Enter on Client Profile that baby “died,” whether death was complication of NBS diagnosis and cause of death.)
- f. “LOST TO FOLLOW-UP,” DOCUMENTATION ON UNUSUAL EVENTS, OR REFUSAL TO TEST, Retain all records and related documentation for **three (3) years** past final disposition/documentation date.

Associated Forms and Documents:

None

Protocol for Purging/Disposing of Records:

Resp. Person	Action
ASC Project Director/ Coordinator	<ul style="list-style-type: none"> • Contacts NBSP Nurse Consultant III/ASC Vendor Agreement Liaison when planning to purge and/or store State records in off-site location. • If ASC wishes to purge records utilizing institution's confidential destruction policies and procedures, send written description to NBSP Nurse Consultant III/ASC Vendor Agreement Liaison for review and approval. • Follows instructions of NBSP Nurse Consultant III/ASC Vendor Agreement Liaison or State Records Management Department representative for packing and shipping of records or confidential destruction (may require witnessed destruction).
NBSP Nurse Consultant III/ ASC Vendor Agreement Liaison	<ul style="list-style-type: none"> • Contacts State Records Management Department representative and coordinates storage or records destruction per State guidelines. • Maintains working knowledge of Department Administrative Manual (HAM) and State Administrative Manual (SAM) as it relates to records retention, storage, and disposal.
CA State Records Management Department Representative	<ul style="list-style-type: none"> • Advises NBSP Nurse Consultant III/ASC Vendor Agreement Liaison on proper procedures for storage as well as appropriate storage facility/shipping protocols or determines destruction procedures for ASC. • Works with NBSP Nurse Consultant and ASC staff to facilitate record disposition.

2.2. Monitoring and Improvement of Hospital and Provider Performance

Policy and General Information:

It is the responsibility of the ASC Project Director and Coordinator(s) to monitor each hospital/provider in the assigned region, providing consultation and technical assistance, education, and training on all aspects of the Newborn Screening Program.

Annual Education/Quality Improvement/Work Plans will be developed based on the specific needs of hospitals/providers in the ASC region and will be submitted to the NBSP Nurse Consultant III/ASC Vendor Agreement Liaison/ by June 1 of each year for the following fiscal year (July 1–June 30).

Progress toward goals and objectives developed in the plan will be measured and reviewed no less often than quarterly by the ASC staff to ensure that change is occurring, and goals will be revised and/or adjusted, if necessary.

ASC staff will attend NBSP statewide meetings and education programs to obtain current information, share successful approaches to problems and issues, and collaborate with staff for program improvement.

Business Objects (BO) and Hospital Evaluation Performance Profile (HEPP) reports are tools used by the NBSP and the ASC to monitor and evaluate hospital performance.

The BO HEPP report is a quality improvement tool that gives California's approximately 300 perinatal facilities feedback on aspects of their performance on their newborn screening responsibilities. Additionally, it enables the State NBSP staff and the program ASCs to monitor hospital performance, identify problems, and assist in correcting them.

Regular Normal Newborn Nurseries and Neonatal Intensive Care Units (NICUs) each receive a separate HEPP.

The HEPP report provides data in the following areas:

- Specific missing data on the TRF
- Timing of specimen collection (e.g., age of babies)

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Effective Date: January 1, 2007
(Compiled/Revised/Modified from Previous Documents)
Last Revision Date: January 10, 2012
(Combined and revised previous protocols 6.4 and 6.5)

- Number of "Inadequates" and "Earlies"
- Average transit time (and delays of specimens)

The HEPP identifies the areas (deficiencies) in which a hospital's performance falls beneath the cutoff set by the State for acceptable performance. However, if a hospital has 10 or more "deficiencies" in a month, a monthly report will be generated and should be sent to the facility. The facility must then send a plan back to the ASC stating the corrective action that will be taken to improve these areas. If a facility receives more than three monthly HEPP reports in a year, the ASC must develop a plan of correction for eliminating or reducing the problem areas.

HEPP reports are generated quarterly and annually (composite of all four quarters). They are automatically developed in Business Objects (BO) from data entered into SIS, which is then exported and stored in the Business Objects "universe." The most current reports are available in "Production Reports," and earlier reports are archived and available in "Archive Reports." Reports are available to the ASC and NBSP staff within approximately two weeks after the reporting time period. They should be reviewed by ASC staff to verify and validate data (as much as possible) and then distributed to the appropriate hospitals.

HEPP reports are identified and "labeled" utilizing the following report content and numbering "codes":

- #1 = NICU
- #2= Regular/Normal Newborn Nursery
- M = Monthly
- A= Annual

Associated Forms and Documents:

None

Protocol:

Resp. Person	Action
ASC Project Director and/or Coordinator	<ul style="list-style-type: none"> • Reviews HEPP monthly and quarterly and distributes to providers within their region; assists them in determining approaches to identified problems. • Uses creative approaches to assess knowledge and learning needs of providers and other target groups (county registrars, midwives, etc.), offers resources and/or provides education and training programs to meet those needs. • Utilizes a variety of resources and methods to attain goals (e.g., training, newsletters, flyers, etc.). • Maintains trend information on progress of providers to decrease deficiencies. • Follows up with providers who have significant numbers of deficiencies (>10/month) and/or ongoing deficiencies that do not improve over time. • Provides feedback regarding compliance with NBSP regulations, policies, and protocols and assists providers to develop their own plans for improvement. • Develops written Corrective Action Plans (with specific and measurable goals, objectives, actions, expected completion dates, and responsible persons) for identified problems and asks providers to sign and endorse them. • Conducts site visits (a minimum of one every three years) to all birthing centers within the region. Maintains written records of site visits and utilizes findings to target new approaches to problems. • Maintains regular phone contact with providers, ascertaining their progress on Corrective Action Plans and providing consultation and assistance as necessary. • Conducts at least six (6) educational programs/year in response to identified problems/needs. • Communicates changes in program regulations, policies, and protocols in a timely manner, ensuring understanding and compliance. • Provides reference and resource materials, as needed or requested. • Evaluates own effectiveness in improving performance and the effectiveness of improvement approaches. • Openly seeks guidance and assistance from Nurse Consultants and other staff at GDSP to improve performance of providers.

2.3. Education and Training Requirements for Area Service Center Staff

Policy and General Information:

To provide guidance for the orientation, education, and training of ASC staff.

Each ASC will have an orientation and ongoing education and training plan for its employees. This plan will be developed using the GDSP/NBSP Orientation Module/Plan as a guideline.

It is recommended that newly hired Program Specialists, Community Liaisons, and Coordinators take the Sickle Cell Counselor Training Course, which is sponsored by GDSP, within the first year of employment with the ASC. This training course should include at least Module I and Part A of Module II.

Project Directors should avail themselves of management training specific to their organization's human resources and employee policies and protocols as well as general education in the principles, techniques, and tools of leadership, supervision, and management.

Project Directors should also initiate ongoing developmental plans to meet the specific developmental needs of each staff member and review these plans with the employee on an annual basis.

Associated Forms and Documents:

None

Protocol:

N/A

2.4. Weekend and Holiday Coverage of Area Service Centers

Policy and General Information:

Essential to the Newborn Screening Program is the rapid follow-up of all positive test results to ensure that babies begin needed treatment as soon as possible. Weekend and holiday coverage ensures that results are handled promptly and that the scope of work is followed.

Weekends are defined as Friday afternoons after 5 PM (1700) through 8:30 AM (0830) Monday mornings.

Holiday coverage begins at 5 PM (1700) the day before the holiday and ends at 8:30AM (0830) the day following the holiday.

The ASC staff is minimally required to have one Coordinator or Program Specialist on call during weekend, holiday, and off hours. While the on-call staff person is not required to be physically present in the ASC, he or she must have the capability to access the ASC voice mail/answering machine during that time.

ASC personnel are responsible to notify Newborn and Prenatal Screening (NAPS) Labs immediately if answering machine/voice mail is out of service or if any other communication or message retrieval problems exist.

All NAPS Labs will process specimens received on Saturday, and some also process on Sundays and holidays.

Associated Forms and Documents:

None

Protocol:

Resp. Person	Action
NAPS Lab Personnel	<ul style="list-style-type: none"> • On weekends and holidays as soon as possible, but no later than the end of the same day test is run, provide the following information for a positive test result on the ASC voice mail/answering machine (ASC staff will not be contacted directly or paged): <ul style="list-style-type: none"> a) Date and time of call b) Name and birth date of infant c) Initial or recall accession number d) Medical record number e) Hospital of birth f) Physician's name and phone number g) Mother's name and phone number h) Analyte and result • Faxes infant's TRF demographic form and the test result to the ASC. • Enters a Confirmation of Contact (CofC) into SIS.
ASC Coordinator or Program Specialist	<ul style="list-style-type: none"> • Between the hours of 9 AM and 4 PM on weekends and holidays, checks answering machine a minimum of every 4 hours (in the morning and again in the afternoon), to retrieve messages and new positive test results. • Notifies the physician of record of the positive test result as soon as possible, but not later than specified in the follow-up protocols. Timeframes begin when the NAPS Lab leaves message on the NBSP ASC message machine. • Notifies family per follow-up protocols. • Enters Tracking Events and/or Case Notes into SIS and sends follow-up letters as soon as possible but not later than the next regular business day.

2.5. Anomalous/Inconsistent NBSP Results Follow-Up

Policy and General Information:

1. “Anomalous/Inconsistent Results” refers to any of the following situations:
 - a. An unexplained large/significant disparity between the initial screening result and subsequent newborn screens or confirmatory tests (e.g., an initial test result that is strongly positive followed by a subsequent negative newborn screen(s) or/confirmatory result).
 - b. Results that are implausible or suspect, possibly suggesting a sample mix-up or tampering (e.g., different hemoglobin patterns of an initial test and subsequent newborn screens or confirmatory tests and/or hemoglobin patterns that are rare in newborns).
 - c. Negative initial screening results of an infant who is subsequently diagnosed with the disorder in question.
2. All test results deemed anomalous or inconsistent must be investigated for one or more of the following reasons:
 - a. If there was a mix-up, a positive screen may actually belong to another baby, who must be identified, located, and tested immediately.
 - b. If it is found that an error occurred during specimen collection/handling or at the laboratory, steps must be taken to prevent it from occurring again, i.e., for quality improvement purposes.
 - c. Information obtained from investigations may assist GDSP in determining if cutoffs or screening procedures need to be changed.
3. Anomalous/Inconsistent results may be reported to the NBSP Investigator/GDSP by babies’ Primary Medical Doctor (PMD) or specialists (who are required by law to report diagnosed cases to GDSP), ASC staff, or other NBS Program/Genetic Disease Lab (GDL) staff.
4. The designated NBSP staff (Nurse Consultant III, GDPS), referred to as “NBSP Investigator,” will investigate anomalous/inconsistent results for all disorders for which the Program screens, with the exception of hemoglobinopathies, which will be investigated by the NBSP Hemoglobin Coordinator.
5. Because of the time-sensitive nature of some anomalous cases, an investigator will be designated and available at GDSP every business day.

6. Investigations of time-sensitive cases described in 2 a. above (i.e., cases in which disparate results may indicate that the true identity of a baby with a positive screen is in question) will be initiated by the Investigator within one business day of receiving the referral. Investigations of other reported cases that are not time-sensitive should be initiated within five business days.
7. When the Investigator determines that screening results warrant an investigation, he/she may request that the GDL analyze the specimen and compare its results to those obtained by the NAPS Lab.
8. All investigation documentation will be kept in the Anomalous/Inconsistent Results Binder. The binder will routinely be kept in a bookcase in the Nurse Consultant Investigator's cubicle.
9. If it is determined that questionable lab results are reflective of NBSP guidelines or protocols not being followed at a perinatal facility (e.g., contaminated specimens or improper identification procedures), the designated ASC staff will work with the appropriate manager in the facility to ensure that identified problems are corrected. The NBS ASC Project Director/Coordinator will submit a Corrective Action Plan (CAP) to the Investigator that includes the problems identified, recommended actions, and plan for continued evaluation /monitoring. Errors or issues related to the NAPS or GDL laboratory testing of specimens will be addressed by the GDL, and the GDL will send the NBSP Investigator documentation of findings and corrective action taken (if indicated) for inclusion in the Anomalous/Inconsistent Results Binder.
10. The Anomalous/Inconsistent Results Binder will be reviewed regularly by the designated Nurse Consultant III to ensure timely follow-up and resolution of all cases. The Chief of NBS Clinical Services Branch (or designee) will be kept informed about all cases that are unresolved a month after initiation of investigation, and the Chief of GDSP or designee will be informed of delays in resolution of investigations.

Associated Forms and Documents:

2.5.1. Anomalous/Inconsistent NBS Results Reporting Form

(To be used by ASCs to report anomalous/inconsistent results to NBSP)

2.5.2. Anomalous/Inconsistent NBS Results Investigation Form

(To be used as a template for information gathering and for documenting investigation)

2.5.3. Anomalous/Inconsistent NBS Results Log

Protocol:

Resp. Person	Action
NBSP, ASC, or GDL Staff or person outside of GDSP	<ul style="list-style-type: none"> • Contacts NBSP and provides information about the case in question. ASC staff aware of case will provide the appropriate NBSP Investigator with relevant information about the case, utilizing the online Anomalous/Inconsistent Results Reporting Form (2.5.1.).
NBS Program Investigator	<ul style="list-style-type: none"> • Initiates this protocol if case is deemed appropriate for investigation and enters Case Note in SIS that investigation is in progress. Collects relevant data on the baby and specimen(s) in question from SIS, the appropriate NBS ASC staff, or MD reporting the case. • Completes Anomalous/Inconsistent Results Investigation Form (2.5.2.) and e-mails form to designated GDL staff, copying Chiefs of Program and Policy, GDL, and NBS Clinical Services Branch (or designee) and to NBSP Nurse Consultant III/ASC Vendor Agreement Liaison. Requests verification of receipt of form from GDL staff. • Places a hard copy of the Investigation Form in the Anomalous/Inconsistent NBS Results Binder, along with a copy of the SIS Case Summary, relevant confirmatory test results, SIS Case Notes, and all correspondence pertaining to the case. • Enters case on Anomalous Results Log (2.5.3.) in Binder, including baby's name, accession number, test in question, and own initials).
Designated GDL Staff	<ul style="list-style-type: none"> • E-mails verification of receipt of Investigation Form to investigator. • Within seven business days of referral, provides investigator with results of investigation, which are entered on the bottom portion of the Investigation Form and sent back to the investigator. <u>If further testing is required, communicates this to the investigator, who will then inform the ASC.</u> • If an error on the part of NAPS Lab or GDL was found, includes corrective action in report. • If investigation is not complete after seven business days, informs investigator, Chiefs of NBS Clinical Services Branch (or designee), GDL, and GDSP (or designee) via e-mail of status of investigation and reason(s) for delay.
NBSP Investigator	<ul style="list-style-type: none"> • If GDL report indicates explanation for inconsistent/anomalous results (e.g., Their specimen analysis produced a different result than the NAPS Lab's result, and it is consistent with the baby's confirmatory test), closes the investigation. (See below.) • If GDL finds no lab errors or reason for anomalous/inconsistent results (e.g., when GDL corroborates NAPS Lab result), discusses next step in investigation with Chiefs of NBS Clinical Services Branch (or designee) and GDSP (or designee). In this instance, investigator should consider

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 (Compiled/Revised/Modified from Previous Documents)
 Last Revision Date: January 10, 2012

	<p>possibility of baby mix-up at hospital. Investigator may</p> <ul style="list-style-type: none"> a) Request that GDL conduct identity testing on NBS specimens (DNA in baby's initial specimen would be compared to DNA of another NBS allegedly collected from the same baby), or b) Have ASC arrange to retest the babies who were in the nursery at the same time as the baby with questionable results.
<p>NBSP Investigator</p>	<ul style="list-style-type: none"> • Once investigation is complete or reason for inconsistent results is found, informs involved ASC Project Director and involved staff of the investigation findings and follow-up. • Writes a summary of the investigation on the Investigation Form and e-mails it to Chiefs, NBS Clinical Services, Program and Policy, and GDL. • Chief, NBS Clinical Services, upon review and approval, signs hard copy of Investigation Form and returns it to investigator. • Closes the investigation by <ul style="list-style-type: none"> a) Signing Investigation Form and placing it and all related documents in the Anomalous/Inconsistent NBS Result Binder. b) Writing date of investigation resolution on anomalous log sheet. c) Making an entry into SIS Case Notes about the investigation findings and any actions taken. • Informs involved ASC and/or reporting physician of investigation outcome.
<p>NBSP Investigator</p>	<ul style="list-style-type: none"> • Reviews the Anomalous/Inconsistent NBS Results Binder regularly to ensure timely follow-up and resolution of all cases. • Informs Chief, NBS Clinical Services Branch (or designee) about all cases that are unresolved a month after initiation of investigation.

AP 3.1 GDSP ASC Site Visits**NBS Area Service Center (ASC) Office On-Site Review Guidelines**

The NBS program review of Area Service Centers includes conducting site visits to each of the seven ASC offices at recommended interval of every three years. Site review will be conducted by the NBS ASC Vendor Agreement Liaison and additional staff as necessary. Site visits can be more frequent if indicated.

Programmatically, reviewers will examine program quality via ASC physical site, review of records and program documentation, Business Objects/Intelligence and/or SIS reports. Interviews with ASC staff regarding aspects of operations. In addition, financial review may be conducted by GDSP staff to include a basic assessment of fiscal systems at the local level. NBS and GDSP staff may examine fiscal documentation for randomly selected quarters to verify allowable costs, appropriate cost allocation, tracking, invoice documentation, timely invoicing, and adequacy of fiscal oversight.

Documentation reviewed may include:

- Randomly selected NBS client caseload data and reports
- NBS Scope of Work objectives and progress
- NBS education curricula and participant materials
- Monthly, Quarterly and Annual report reviews
- Evaluation tools and data
- ASC budgets documentation
- State owned equipment
- Monthly/Quarterly Invoices
- Mileage logs and travel/training receipts
- Staffing, hiring, and vacancy reports

The written review generated after the Site Visit may include:

FINDINGS AND OBSERVATIONS

Program Quality and Administration

Fiscal Integrity and Administration

CONCLUSIONS**RECOMMENDATIONS****REQUIRED CORRECTIVE ACTIONS**

3.2. Contingencies for Unplanned Events, Emergencies, or Disasters Affecting the Genetic Disease Screening Program and the Newborn Screening Program

Policy and General Information:

Purpose of Plan: To assure timely results reporting, follow-up, and treatment of infants in the event of unplanned events (earthquake, tsunami, fire, hurricane, explosion etc.) that impacts the operation of the GDSP Newborn Screening Program.

Definition of unplanned events, emergencies, disasters: The result of any action by person(s), machine(s), or forces of nature that may cause operational disruptions for two days or longer in the NBSP and/or the Area Service Centers (ASC).

CDPH Emergency Information Hotline: 1 (888) 273-4431

In the event of a major emergency or a disaster affecting a CDPH office, state employees can receive instructions and guidance subsequent to an emergency (e.g., return to work messages). The Department's Emergency Information Hotline routes to three (3) regional messages that include information as it relates to CDPH and the current situation within a specific region. The regions are as follows:

- **Press 1** for the CDPH Inland Region, which includes Bakersfield, Chico, Elk Grove, Fresno, Redding, Sacramento, West Sacramento, and Stockton.
- **Press 2** for the CDPH Coastal Region, which includes Daly City, Monterey, Richmond, San Jose, and Santa Rosa.
- **Press 3** for the CDPH Southern Region, which includes Anaheim, Brea, Carpinteria, Gardena, Granada Hills, Long Beach, Los Angeles, Nipomo, Ontario, Oxnard, San Bernardino, San Diego, Santa Ana, and West Covina.

During periods when there is nothing to report, the message will indicate "Currently all CDPH (specific region) facilities are open and ready for business during normal working hours. Please remember that this service will be updated whenever an emergency situation arises at any CDPH (specific region) facility. Thank you for calling the California Department of Public Health Emergency Information Hotline."

In addition to the CDPH Emergency Information Hotline, all programs are to maintain effective emergency communication and notification procedures. Emergency Notification telephone trees are to be established and continuously maintained. The telephone tree is to remain confidential and will consist of names, office, and home telephone numbers. Please keep one list in a safe place at work and another copy at your home so it is easily accessible.

Associated Forms and Documents:

- 3.2.1. Potential Offsite Locations for Disaster Plan
- 3.2.2. Redistribution of Workload for Unavailable ASC(s)
- 3.2.3. Contractors/Agencies to be Notified in Event of Disaster

Protocol:

N/A

3.3. NBSP Area Service Center (ASC) Vendor Agreement Information

Policy and General Information:

N/A

Associated Forms and Documents:

- 3.3.1. Area Service Center (ASC) Vendor Agreement and Scope of Work (SOW) (FY 2011–2014)
- 3.3.2. Genetic Disease Screening Program (GDSP) Administrative Policies (FY 2011–2014)
 - 3.3.2.1. Roles & Duties of ASC Positions—General Guidelines (FY 2011–2014)
- 3.3.3. NBS ASC Vendor Agreement Reporting Requirements (Exhibit A—Attachment 1 of Vendor Agreement) (FY 2011–2014)
 - 3.3.3.1. Progress Report Signature Form
 - 3.3.3.2. ASC Annual Quality Improvement Plan
 - 3.3.3.3. Site Visit/In-Service Log
 - 3.3.3.4. Corrective Action Plan (CAP)
 - 3.3.3.5. Corrective Action Plan (CAP) Log

Protocol:

N/A

3.4 CCS Center Vendor Agreement Information

Policy and General Information:

N/A

Associated Forms and Documents:

3.4.1. Metabolic Center Vendor Agreement and Scope of Work (SOW)

3.4.2. Endocrine Center Vendor Agreement and Scope of Work (SOW)

3.4.3. Hemoglobin Center Vendor Agreement and Scope of Work (SOW)

3.4.4. Cystic Fibrosis Center Vendor Agreement and Scope of Work (SOW)

Protocol:

N/A

Appendix:

Associated Forms and Documents

1.1.1. Security and Confidentiality Acknowledgement (CDPH 2420 1/11)

State of California—Health and Human Services Agency

California Department of Public Health

SECURITY AND CONFIDENTIALITY ACKNOWLEDGEMENT

I have read the Information Security Policy (Public Health Administrative Manual (PHAM) Chapter 9-1000) and the Privacy Policy (PHAM Chapter 11-4000), and will comply with the security and privacy requirements indicated in both policies. Also, I understand the need to:

1. Exercise due care to preserve information integrity and confidentiality.
2. Treat passwords as confidential information and do not share them with anyone.
3. Take reasonable precautions to ensure the protection of CDPH information from unauthorized access or destruction.
4. Conduct all Internet and/or E-mail activities in a professional, lawful, and ethical manner, including the use of and development of content for the Internet.
5. Use CDPH information and resources for CDPH business purposes.
6. Download and/or copy only the minimum amount of information required to perform necessary business functions.
7. Encrypt all electronic files that contain Department information when stored on any removable media type device (i.e. USB thumb drives, floppies, CD/DVD, tape backup, etc.)
8. Notify my supervisor and the CDPH Information Security Office of a possible or actual information security incident including, but not limited to:
 - a. Theft, loss, damage, unauthorized destruction, unauthorized modification, misuse, or unintentional or inappropriate release of any CDPH classified data or Protected Health Information (PHI). (Refer to HAM Section 6-1050 for definition of "classified" and "PHI".)
 - b. Inappropriate Use & Unauthorized Access - This includes actions of State employees and/or non-State individuals that involve tampering, interference, damage, or unauthorized access to State computer data and computer systems. Examples are: successful virus attacks, website defacements, server compromises, and denial of service attacks.
 - c. Equipment - Theft, damage, destruction, or loss of State-owned Information Technology (IT) equipment, including mobile computing devices, or any electronic devices containing or storing confidential, sensitive, or personal data.
 - d. Computer Crime - Use of a State information asset in commission of a crime.
 - e. Any other incident that violates the Department's Information Privacy and Security Policy.

Employee name (please print)	
Division	Telephone Number ()
Employee's signature	Date
Supervisor's signature (permitting access)	Date

CDPH 2420 (01/11)

1.1.2. Breach Incident Reporting Form (CDPH 2375 11/07)

State of California—Health and Human Services Agency

California Department of Public Health

CDPH BREACH/INCIDENT REPORTING FORM

SECTION A: CONTACT INFORMATION		
REPORTED BY:	PROGRAM:	DATE REPORTED:
TITLE:	TELEPHONE:	
ALTERNATE CONTACT:	EMAIL:	
SECTION B: IDENTIFYING DETAILS WHEN APPLICABLE		
MAKE/MODEL:	SERIAL NUMBER:	
STATE TAG NUMBER:	COMPUTER NAME:	
WAS CONFIDENTIAL DATA INVOLVED, IF SO DESCRIBE:		
WAS DATA ENCRYPTED, DESCRIBE:		
ESTIMATED VALUE OF THE COMPUTING DEVICE:		
SECTION C: INCIDENT DETAILS		
DATE AND TIME OF INCIDENT:		
TYPE OF MEDIA: <input type="checkbox"/> ELECTRONIC <input type="checkbox"/> PAPER		
TYPE OF DEVICE: <input type="checkbox"/> PC <input type="checkbox"/> LAPTOP <input type="checkbox"/> BLACKBERRY/PDA <input type="checkbox"/> CELL PHONE <input type="checkbox"/> OTHER (DVD/CD/UFD)		
CLASSIFICATION OF DATA: <input type="checkbox"/> CONFIDENTIAL <input type="checkbox"/> SENSITIVE <input type="checkbox"/> PERSONAL <input type="checkbox"/> N/A (explain below)		
TYPE OF INCIDENT: <input type="checkbox"/> THEFT <input type="checkbox"/> LOSS <input type="checkbox"/> DAMAGE <input type="checkbox"/> DESTRUCTION <input type="checkbox"/> MISUSE <input type="checkbox"/> UNAUTHORIZED MODIFICATION / RELEASE OF INFORMATION (complete Sections B, D, E)		
DESCRIPTION OF INCIDENT:		
INDIVIDUALS (BENEFICIARIES/EMPLOYEES/CONTRACTORS/ETC.) INVOLVED/AFFECTED BY INCIDENT:		
PROGRAM AREA(S) INVOLVED WITH INCIDENT:		
WERE STATE EMPLOYEES INVOLVED: <input type="checkbox"/> Yes <input type="checkbox"/> No		
LOCATION ADDRESS OF INCIDENT:		
INCIDENT REPORTED TO (CHP, LAPD, ETC.):		
POLICE REPORT NUMBER:		
HAVE THOSE RESPONSIBLE FOR THE INCIDENT BEEN IDENTIFIED?: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		
IMPACT OF INCIDENT:		
ENTAC CONTACTED: <input type="checkbox"/> Yes <input type="checkbox"/> No	INCIDENT #	OFFICER NAMES:
ESTIMATED COST OF INCIDENT:		

State of California—Health and Human Services Agency

California Department of Public Health

SECTION D: CORRECTIVE ACTIONS		
ACTIONS TAKEN TO PREVENT RECURRENCE:		
ADDITIONAL RECOMMENDED ACTIONS:		
ESTIMATED COST OF CORRECTIVE ACTION: \$		
SECTION E: REPORTING SOURCE/ISO SIGNATURE		
PREPARER NAME:	TITLE:	TELEPHONE:
ISO SIGNATURE		DATE REPORTED:

1.3.2. Cover Letter for Release of Results

(To be used for both lay and medical requestors)



State of California—Health and Human Services Agency
California Department of Public Health



RON CHAPMAN, MD, MPH
Director

EDMUND G. BROWN JR.
Governor

DATE

Per your request, attached are the Newborn Screening (NBS) results from the California Genetic Disease Screening Program (GDSP).

Please note that these are the results of a screening test. Screening is defined as the testing of a group of people to identify those who are at risk for having a specific disease even though they may seem healthy. This result does not constitute diagnosis or the need for treatment. Therefore, further testing and evaluation by the baby's health care provider or a specialist are needed to make the diagnosis. Please contact your chosen medical or health professional to assist you in reviewing and interpreting these results.

The Newborn Screening Program will not identify all newborns with conditions. The possibility of a disorder should never be ruled out solely on the basis of the NBS results. Any signs or symptoms of a disorder should be followed up immediately.

Sincerely,

Erica G. Gordon, MA
Chief, Newborn Screening Clinical Services Branch
Newborn Screening Program

1.4.1. Consent for Disclosure and/or Release of Dried Blood Spots from GDSP



State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN JR.
Governor

**CONSENT FOR DISCLOSURE AND/OR RELEASE OF
DRIED BLOOD SPECIMEN FROM GDSP**

The undersigned hereby authorizes the release of Newborn Screening Specimen from the records of the Genetic Disease Screening Program.

FOR NEWBORN PATIENT

Name: _____

Gender: _____ Date of Birth: _____

Hospital Of Birth: _____

Mother's Full Name (including maiden name): _____

Mother's Date of Birth: _____

Family's Address at Time of Birth: _____

RELEASE TO

Name: _____

Address: _____

Phone: _____ Fax #: _____

REASON FOR REQUEST

This authorization will expire on (Enter Date) _____.

You have the right to retain a copy of this consent. You have the right to revoke this consent at any time by writing to Chief, Genetic Disease Screening Program at 850 Marina Bay Parkway, Richmond, CA 94804 as stated in our privacy notice. Revocation of this consent does not eliminate your responsibilities for payment for services received. The Genetic Disease Screening Program is not responsible for further disclosures of the information by other parties that may result from complying with this consent.

(Parent/Patient/Legal Guardian Signature) (Date)

I understand that any person who requests or obtains any record containing personal information from the California Department of Public Health under false pretenses will be guilty of a misdemeanor and fined up to \$5,000 or imprisoned up to one year or both.

Revised: 11/2011

Genetic Disease Screening Program • Richmond, CA 94804
(510) 412-1502 • (510) 412-4857 FAX
Internet Address: www.cdph.ca.gov

1.4.2. Request to Restrict Use and Disclosure of Personal Information by Parent, Guardian or Personal Representative (CDPH Form 6241 (4/09))

STATE OF CALIFORNIA—HEALTH AND HUMAN SERVICES AGENCY

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
PRIVACY OFFICE

CONFIDENTIAL

REQUEST TO RESTRICT USE AND DISCLOSURE OF PERSONAL INFORMATION BY PARENT, GUARDIAN OR PERSONAL REPRESENTATIVE

You have the right to request the California Department of Public Health Services (CDPH) to restrict the use and disclosure personal information to carry out treatment, payment or operations. You also have the right to request CDPH not to disclose personal information to a family member, relative, or friend involved with care or payment for the individual's health care. NOTE: CDPH may refuse to agree to your requested restriction(s) but will notify you of its refusal in its response to your request. This form must be accompanied by a photocopy of your California driver's license, Department of Motor Vehicles Identification Card, or other valid identification. You will also need to send another type of documentation verifying your address (see below). **Mail or fax this completed form to:**

Privacy Officer
California Department of Public Health
P.O. Box 997377, MS 0506
Sacramento, CA 95899-7377
(916) 440-7714 (fax)

INDIVIDUAL WHOSE INFORMATION YOU ARE REQUESTING TO RESTRICT THE USE AND DISCLOSURE OF PERSONAL INFORMATION			
LAST NAME: [REDACTED]	FIRST NAME: [REDACTED]	MIDDLE INITIAL: [REDACTED]	
ADDRESS: [REDACTED]	CITY/STATE: [REDACTED]	ZIP CODE: [REDACTED]	
BENEFICIARY ID NUMBER:	DATE OF BIRTH:	DATE OF DEATH (if applicable): Death Certificate Must Be Attached	
PARENT, GUARDIAN, OR PERSONAL REPRESENTATIVE INFORMATION			
LAST NAME: [REDACTED]	FIRST NAME: [REDACTED]	MIDDLE INITIAL: [REDACTED]	
ADDRESS: [REDACTED]	CITY/STATE: [REDACTED]	ZIP CODE: [REDACTED]	
DAYTIME TELEPHONE NUMBER (Required): [REDACTED]	EVENING TELEPHONE NUMBER: [REDACTED]	EMAIL ADDRESS: [REDACTED]	BEST HOURS TO REACH YOU: [REDACTED]
WHAT LEGAL AUTHORITY DO YOU HAVE TO RESTRICT THE USE AND DISCLOSURE OF PERSONAL INFORMATION ABOUT THE INDIVIDUAL LISTED ABOVE?			
<input type="checkbox"/> PARENT	<input type="checkbox"/> CONSERVATOR		
<input type="checkbox"/> GUARDIAN	<input type="checkbox"/> EXECUTOR OF WILL		
<input type="checkbox"/> MEDICAL POWER OF ATTORNEY	<input type="checkbox"/> OTHER		
NOTE: YOU MUST ATTACH LEGAL DOCUMENTATION TO VERIFY THAT YOU ARE THE PARENT, CONSERVATOR, GUARDIAN, EXECUTOR OF A DECEDENT'S WILL, OR HAVE MEDICAL DECISION-MAKING AUTHORITY FOR THE INDIVIDUAL.			
DIRECTIONS			
WHICH CDPH PROGRAM(S) HAS/HAVE THE PERSONAL INFORMATION OF THE INDIVIDUAL ABOVE THAT YOU WANT TO RESTRICT USE AND DISCLOSURE OF?			
<input type="checkbox"/> AIDS Drug Assistance Program (ADAP)	<input type="checkbox"/> Prenatal Screening Program		
<input type="checkbox"/> AIDS Medi-Cal Waiver Program (MCWP)	<input type="checkbox"/> Prostate Cancer Treatment Program (IMPACT)		
<input type="checkbox"/> Children's Treatment Program (CTP)	<input type="checkbox"/> Therapeutic Monitoring Program (TMP)		
<input type="checkbox"/> Emergency Medical Services Appropriation (EMSA)	<input type="checkbox"/> Viral and Rickettsial Disease Laboratory (VRDL)		
<input type="checkbox"/> Every Woman Counts (CDS:EWC)	<input type="checkbox"/> OTHER (Please list CDPH program(s) which may have the personal information) _____		
<input type="checkbox"/> Family Planning Access, Care, & Treatment (FPACT)			
<input type="checkbox"/> Newborn Screening Program			
<input type="checkbox"/> Refugee Health Services	<input type="checkbox"/> UNKNOWN (If this box is checked, we will call you to assist in determining which CDPH program(s) may have the personal information you are requesting we restrict the use and disclosure.)		

Appendix

CHECK ALL THAT APPLY	
<input type="checkbox"/>	I REQUEST THAT THE CALIFORNIA DEPARTMENT OF PUBLIC HEALTH RESTRICT USE AND DISCLOSURE OF THE INDIVIDUAL'S PERSONAL INFORMATION IN CARRYING OUT TREATMENT, PAYMENT, OR HEALTH CARE OPERATIONS AS FOLLOWS:
<input type="checkbox"/>	I REQUEST THAT THE CALIFORNIA DEPARTMENT OF PUBLIC HEALTH RESTRICT THE DISCLOSURE OF PERSONAL INFORMATION FROM THE FOLLOWING PERSONS:
PLEASE PROVIDE THE NAMES OF ANY FAMILY MEMBERS, RELATIVES... TO WHOM YOU DO NOT WANT CDPH TO DISCLOSE INFORMATION IN THE SPACE ABOVE.	
IDENTIFYING INFORMATION IS REQUIRED	
<input type="checkbox"/>	COPY OF ADDRESS VERIFICATION ATTACHED TYPE: _____ (UTILITY BILL, PHONE BILL, DRIVER'S LICENSE, ETC.)
<input type="checkbox"/>	COPY OF IDENTIFICATION ATTACHED TYPE: _____ (CA DRIVER'S LICENSE, CA DMV IDENTIFICATION CARD, BIRTH CERTIFICATE, BENEFITS IDENTIFICATION CARD, MANAGED CARE CARD, STATE OR FEDERAL EMPLOYEE ID CARD) NUMBER: (____) _____
(IF NO IDENTIFICATION IS ATTACHED, YOUR SIGNATURE MUST BE NOTARIZED.)	
NOTARIZED BY _____ ON _____ (DATE)	
NOTARY PUBLIC NUMBER _____	
UNOFFICIAL UNLESS STAMPED BY NOTARY PUBLIC:	
I DECLARE UNDER PENALTY OF PERJURY THAT THE INFORMATION ON THIS FORM IS TRUE AND CORRECT.	
REPRESENTATIVE SIGNATURE: _____ DATE: _____	
DEPARTMENT EMPLOYEE PROCESSING/MAINTAINING THIS REQUEST FOR RESTRICTION ON USE AND DISCLOSURE OF PERSONAL INFORMATION	
THIS SECTION TO BE COMPLETED BY DEPARTMENT STAFF	
_____ (Name and Title)	
_____ (Organization within Department)	
_____ (Telephone Number)	
_____ (Mail Stop Number)	

PRIVACY STATEMENT (CA CIVIL CODE SECTION 1798.17)
THE INFORMATION COLLECTED ON THIS FORM IS USED TO PROCESS YOUR REQUEST TO RESTRICT USE AND DISCLOSURE OF PERSONAL INFORMATION ABOUT AN INDIVIDUAL YOU LEGALLY REPRESENT THAT IS MAINTAINED BY THE CALIFORNIA DEPARTMENT OF PUBLIC HEALTH (DEPARTMENT). THE INFORMATION WE COLLECT FROM YOU ON THIS FORM WILL BE KEPT CONFIDENTIAL AND ON FILE AT THE DEPARTMENT, AS REQUIRED BY LAW. ALL INFORMATION REQUESTED ON THE FORM IS MANDATORY PURSUANT TO TITLE 45, CODE OF FEDERAL REGULATIONS, SECTION 164.522. NOT SUPPLYING THE INFORMATION REQUESTED WILL RESULT IN THE DENIAL OF YOUR REQUEST. ANY INFORMATION PROVIDED MAY BE DISCLOSED TO THE CALIFORNIA STATE AUDITOR, THE CALIFORNIA OFFICE OF HEALTH INFORMATION INTEGRITY, THE CALIFORNIA OFFICE OF INFORMATION SECURITY AND PRIVACY PROTECTION, THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES OR TO OTHER STATE AND FEDERAL AGENCIES AS REQUIRED BY LAW.
YOU HAVE THE RIGHT TO REVIEW THE RECORDS WE KEEP ABOUT YOU DURING NORMAL BUSINESS HOURS. THE CALIFORNIA DEPARTMENT OF PUBLIC HEALTH PRIVACY OFFICER WILL, UPON REQUEST, INFORM YOU REGARDING THE LOCATION OF YOUR RECORDS AND THE CATEGORIES OF ANY PERSONS WHO USE THE INFORMATION IN THOSE RECORDS. FOR MORE INFORMATION, CONTACT THE CALIFORNIA DEPARTMENT OF PUBLIC HEALTH, PRIVACY OFFICE, USING THE FOLLOWING CONTACT INFORMATION: CALIFORNIA DEPARTMENT OF PUBLIC HEALTH, OFFICE OF LEGAL SERVICES, PRIVACY OFFICE, MS 0506, P.O. BOX 997377, SACRAMENTO, CALIFORNIA 95899-7377 OR BY PHONE 1-877-421-9634.

2.5.1. Anomalous/Inconsistent NBS Results Reporting Form

Anomalous/Inconsistent NBS Results *Reporting Form*

Reported to (GDSP Investigator): _____ Date Submitted: _____

Submitted by: _____ ASC: _____

Child's name: _____ AKA: _____

NBS Accession #: _____ DOB: _____

Gestational Age: _____ Birth Weight: _____

Reason for Concern: (include contact source, issues/results of concern, date received)
e.g., Baby had a strongly positive TSH screen, and low negative confirmatory TSH

e.g., Received call 3/9/11 from endocrinologist Dr. J. Smith, that this 3-month old baby with a neg. NBS was just diagnosed with PCH and started on Synthroid on 3/2. See faxed H&P

e.g., call from S. Jones, CGC, Stanford Metabolic Center reporting that this baby's confirmatory was negative, and they have never seen a _____ value this high and not be a case.

Confirmatory or Subsequent Test Results/Dates Collected (if in SIS, don't have to repeat here):

Clinical Presentation: clinical signs and symptoms as noted by clinician who examined the infant/child; or report of unusual findings from parent - fax H&P, progress notes, if possible:
(e.g., Baby has been lethargic, mottled, constipated, and hypothermic)

Maternal Hx (meds mom was on during pregnancy, diagnosed condition, etc.):

For baby with a high NBS TSH and a negative confirmatory - Was mom on PTU during pg? If so, explains high positive screen, so no need to report this case.

For CAH, was mom on any hormones/steroids during pg? Was she given dose of steroid to mature fetus' lungs?

For CF, was there pre-natal screening for CF?

MS/MS: Does mom have a metabolic condition?

Miscellaneous/Other Comments:

6/16/11

2.5.1 Anomalous/Inconsistent Results Investigation Form

Date Reported: _____ Name of Reporter: _____ Contact Number: _____

Infant's Name: _____ AKA: _____ Date of Birth: _____

Sex: _____ Gestational Age at Birth: _____

Birth Weight: _____

Disorder(s) Diagnosed: _____ Date of Diagnosis: _____

Treatment: _____ Date Treatment Started: _____

Initial Accession Number: _____ **I Number:** _____

Analyte(s)	Values	Reference Range

Age at Collection: _____ Method of Collection: _____

Disorder in Question: _____

Other (or 2nd) NBS Accession #: _____ **I Number:** _____

Date Collected: _____ Method of Collection: _____ Result in Question: _____

Confirmatory Tests Results:

Date	Test/Results:	Ref. Range:	Laboratory:

Comments for Client History _____

Relevant Maternal History (including meds during pregnancy) _____

Comments/Request:

NBSB Investigator: _____ Date: _____

GDL Action Taken, Findings, Corrective Action (if indicated), Conclusions/Recommendations:

Person Completing GDL Report: _____ Date: _____

Reviewed by: _____
Rasoul Koupaei, PhD, DABCC, FACB
Chief, Genetic Disease Laboratory Branch



Summary (including conclusions, i.e., reasons for inconsistent or anomalous results, and any follow-up activities taken):

NBSB Investigator: _____

Reviewed by:

Richard Olney, MD, MPH
Division Chief, Genetic Disease Screening Program

3.2.1. Potential Offsite Locations for Disaster Plan

First choice for offsite work locations would be for the staff to work at home, if a computer, the Internet, and a printer are available, or at the home of another NBSF staff person.

The next option would be to work at another State office location. The closest office would be the State Department of Rehabilitation—Richmond Branch, (510) 232-7062, 1003 W. Cutting Blvd., Suite #100, Richmond, CA 94804.

DHS Division Occupational Safety and Health, (510) 286-7000, is located at 1515 Clay Street. This location is accessible by BART (12th Street/City Center station). Health Services Department is also at 1515 Clay St # 401, Oakland, CA 94612, (510) 286-0760. DMV offices may possibly also be used in an emergency.

Copy and print centers, Internet cafés, or postal business are also possibilities. The closest businesses of this type to the California Public Health Department, Richmond Marina Bay location are:

- Staples, 11545 San Pablo Ave, El Cerrito, CA 94530, (510) 231-0388 (copy, print, and shipping services)
- Richmond Public Library, 450 Civic Center Plaza (25th and McDonald Ave.), Richmond, CA 94804, (510) 620-6521. Computer use: one hour free/day. Obtain library card to reserve. (Internet, print, and copy services)
- UPS Store, 3020 El Cerrito Plaza, El Cerrito, CA 94530, (510) 528-9444 (copy, print, and shipping services)
- FedEx Office Print & Ship Center, 9889 San Pablo Avenue, El Cerrito, CA 94530, (510) 528-5071 (Internet, commercial print, shipping, and copy services)

3.2.2. Redistribution of Workload for Unavailable ASC(s)

UNAVAILABLE ASC	TRANSFER ALL TO
93 Kaiser North	94 Kaiser South
94 Kaiser South	93 Kaiser North
95 Stanford	96 CHCC or Kaiser North
96 CHCC	95 Stanford or Kaiser South
97 UCLA	98 Harbor or *95 CHCC
98 Harbor	97 UCLA or *99 RCHSD
99 RCHSD	98 Harbor
	*if all of LA is unavailable

Plans may be adjusted during an actual emergency/disaster depending on the severity and expected length of disruption of services.

3.2.3. Contractors/Agencies to be Notified in Event of Disaster

CONTRACTOR	CONTACT	PHONE NUMBER	RESPONSIBILITY TO CALL
Public Health Institute	Vicky Torres	(916) 285-1224	Erica Gordon Keiko Noriye (back up)
Sickle Cell Subs and HRSA SC Contractors	CHO—Jayshree Merchant	(510) 428-3365	Norah Ojeda
	SCDFC—Mary Brown	(310) 693-0247	
Metabolic Centers	Clinic Coordinators/ Project Directors (See list)		Carole Klein
Endocrine Centers	Clinic Coordinators/ Project Directors	(See list)	Shellye Lessing
Cystic Fibrosis Centers	Clinic Coordinators/ Project Directors	(See list)	Tracey Bishop
Hb Centers	Clinic Coordinators/ Project Directors	(See list)	Carole Klein
CCS Main Office	Kathy Chance, M.D.		Robin Thomas NC III (back up)
NAPS Labs	Clinic Coordinators/ Project Directors	(See list)	Revelyn Cayabyab
Confirmatory Labs	Metabolic (Quest)		Leslie Gaffney
	ARUP Hemoglobin (CHRC0)		Leslie Gaffney Shellye Lessing
	Biotinidase Def (Stanford)		Tracey Bishop
	CF Mutation & Sequencing (Stanford)		Tracey Bishop
Courier	GSO		Tina Santos
Mailing Vendor	O-Neil		Revelyn Cayabyab
Storage and Distribution	Sierra Business— Linda Williams	(916) 344-8450	Norah Ojeda Irene Mandujano (back up)
Translation Services	Accent on Languages—Tram Dyck	(510) 655-9470	Norah Ojeda Irene Mandujano (back up)

Appendix

SCOPE OF WORK

(confd)

The Vendor shall work toward achieving the following goals within the assigned geographic area and will accomplish the following objectives. This will be accomplished by performing the specified activities and evaluating the results using the listed methods to focus on process and/or outcome. All activities will be carried out in accordance with the Newborn Screening regulations, protocols and procedures. During an emergency, geographic areas may be temporarily reassigned.

Goals No. 1 & 2 (Continued)

MEASURABLE OBJECTIVES	IMPLEMENTATION ACTIVITIES	TIMELINE	METHOD(S) OF EVALUATION PROCESS AND/OR OUTCOME OF OBJECTIVE(S)
<p>2. The follow-up (i.e., repeat or confirmatory testing) of initial test that are positive, inadequate, obtained after a transfusion, or possibly collected early, i.e. under 12 hours of age, will occur within established time frames.</p> <p>a. For initial positives: Confirmatory specimens will be collected and sent to a lab as soon as possible but no later than 5 days after MU notification.</p> <p>b. For inadequate and early specimens: Repeat specimens will be collected and sent to lab as soon as possible but no later than 5 days after MD notification.</p> <p>c. For specimens possibly collected early: Babies verified to have been collected early (or whose age at collection could not be determined) will get a second NBS test.</p> <p>d. For babies verified to have been initially screened post-transfusion, whole blood DNA testing by a hemoglobin reference lab may be offered</p>	<p>*Assist the newborn's physician or hospital in obtaining blood specimens on infants whose initial specimens were positive, early, inadequate or collected after a transfusion. For early tests: Verify times/dates of birth and specimen collection.</p> <p>*Send letters to all parents and physicians of newborns requiring further actions, with the exception of newborns remaining in hospitals.</p> <p>*Provide newborn's physician with appropriate specimen collection forms and instructions for specimen collections.</p> <p>*Assist MD/hospital to collect a specimen.</p> <p>*Inform newborn's physician that a specimen was not obtained and offer assistance in arranging specimen collection.</p>	<p>At time of MD notification</p> <p>within 3 days of reporting out NBS results</p> <p>At time of MD notification</p> <p>At time of MD notification</p> <p>At time of MD notification</p>	<p>Maintain in ASC file the number of possibly early tests and inadequates, and list, by specific disease, the number of positives. - SIS BO reports</p> <p>Retain copies of letters in NBS ASC files.</p> <p>Maintain in ASC file the time required to obtain adequate samples and the number for which no sample could be obtained (i.e. lost to follow-up, refusals).</p> <p>Maintain in ASC file: - number of actual early collections - number of those flagged as possibly early that were actually collected after 12 hours.</p> <p>Tracking events, case notes</p>

SCOPE OF WORK

(cont'd)

The Vendor shall work toward achieving the following goals within the assigned geographic area and will accomplish the following objectives. This will be accomplished by performing the specified activities and evaluating the results using the listed methods to focus on process and/or outcome. All activities will be carried out in accordance with the Newborn Screening regulations, protocols and procedures. During an emergency, geographic areas may be temporarily reassigned.

Goals No. 1 & 2 (Continued)

MEASURABLE OBJECTIVES	IMPLEMENTATION ACTIVITIES	TIMELINE	METHOD(S) OF EVALUATION PROCESS AND/OR OUTCOME OF OBJECTIVE(S)
<p>3. Babies not screened at birth will be identified, located, and screened.</p> <p>a. Those discharged from a hospital without a specimen obtained will have a specimen collected and sent to lab within 48 hours of MD notification.</p> <p>b. Those born out of hospitals and not subsequently admitted to a hospital will have a specimen collected and sent to lab within 48 hours of notification of ASC.</p>	<p>*Notify parents of NBS requirements and provide assistance in arranging specimen collection.</p> <p>*Offer MD/hospital assistance in arranging for specimen collection.</p>	<p>At time of MD notification</p> <p>At time of MD notification</p>	<p>Maintain in ASC file the number of NBS-NOs, out-of-hospital births, and missing results as well as outcomes of follow-up, case notes, SIS case notes, and reports</p> <p>Maintain in ASC File the number of specimens collected/sent - results in SIS</p>
<p>4. Consultation is provided to primary care providers regarding interpretation of the confirmatory screening test results and diagnosis and management of disorders detected.</p>	<p>*Provide assistance to newborns' physicians regarding referrals to appropriate CCS Centers and/or medical specialists, and recommended diagnostic procedures and treatment.</p>	<p>At time of MD notification</p>	<p>Submit any changes in NBS Medical Consultants or Medical Specialists to the State for approval.</p> <p>Documentation in SIS</p>
<p>5. Information, assistance and support is provided to parents of infants with positive, or early, inadequate tests.</p>	<p>*Answers parents' questions</p> <p>*Facilitates transportation, translation services</p>	<p>on-going</p>	<p>Documentation in SIS</p>
<p>6. All infants with confirmed cases are evaluated and treatment is initiated within time frames that meet State standards.</p>	<p>*Monitor age of newborns at initiation of treatment and identify causes for delays, defined as: > 8 days for galactosemia > 14 days for PKU > 14 days for hypothyroidism > 8 weeks for hemoglobinopathies</p>	<p>monthly</p>	<p>SIS reports Corrective action plan for delays Document delays, reasons for delays in monthly report</p>
	<p>*Contact newborn's physicians to obtain information about diagnosis and treatment.</p> <p>*For babies with hyperphenylalaninemia facilitate the collection/handling of specimens for bioprotein testing, when needed.</p>	<p>on-going</p> <p>within 48 hours of Metabolic center specialist notification</p>	<p>State staff reviews cases in which treatment was delayed.</p> <p>Document number of specimens sent for bioprotein testing, Maintain in ASC file as needed.</p>

Appendix

SCOPE OF WORK

(cont'd)

The Vendor shall work toward achieving the following goals within the assigned geographic area and will accomplish the following objectives. This will be accomplished by performing the specified activities and evaluating the results using the listed methods to focus on process and/or outcome. All activities will be carried out in accordance with the Newborn Screening regulations, protocols and procedures. During an emergency, geographic areas may be temporarily reassigned.

Goals No. 1 & 2 (Continued)

MEASURABLE OBJECTIVES	IMPLEMENTATION ACTIVITIES	TIMELINE	METHOD(S) OF EVALUATION PROCESS AND/OR OUTCOME OF OBJECTIVE(S)
7. Timely transmission of data via the State's computer network will occur between the State and the Area Service Center.	*Maintain a communications device in accordance with State specifications. The computer network shall operate on specified data lines and shall provide hard copy output of transmissions.	on-going	To insure system compatibility, any proposed changes must receive prior written approval from the State.
	*Log on at least once daily to the central site computer (SIS) for reception of data, contingent upon availability of the State's computer system. Communication with the State shall be the first priority in the use of communication devices.	daily	Notify the State immediately of any problems in data transmission. Review for accuracy of data.
	*Assure proper hardware and software functioning.	daily	
	*Enter data into State's central site computer (SIS) within 24 hours of data acquisition.	on-going	State staff will monitor timeliness, completeness and accuracy of data entered, using SIS Business Object reports.
	*Enter Tracking Events and case notes documenting activities and calls between ASC, hospitals and newborn's physicians on same day of calls.	daily	
	*Upon finding or being informed that a case is resolved, enter appropriate resolution data into SIS computer record.	by the next business day	SIS Reports
8. Consultation and technical assistance is provided to NBS providers and others with NBS responsibilities, i.e. physicians, hospitals with perinatal facilities and free-standing children's hospitals, public health departments, midwives, primary care providers, etc., in implementation and interpretation of state regulations.	*Conduct site visits to each of the perinatal facilities within the region.	a minimum of once every three years	In monthly reports include: State number and names of hospitals visited including date of visit, personnel contacted and purpose and outcome of visit.
	*Provide phone and on-site consultation.	upon request or when needed	Maintain log of contacts or hospital file, as needed.
	*Communicate up-to-date information on program regulations, policies, and protocols by a variety of methods (e.g., newsletters, meetings, presentations, etc.)	on-going	Expected outcomes: Acceptable rate of inadequates. Decrease in delays in obtaining repeats or confirmatory tests, low deficiency rate on HEPP Report, Increase in NBS-OH's sent to state from registrar's offices, etc.
	*Provide reference and resource materials as needed.	when requested	All mass mailings addressing NBS Program policies and protocols must be submitted to contract liaison for approval prior to mailing. - Contact logs Patient education materials that are not on the State approved list must be submitted to the contract liaison for review and approval prior to distribution.

Appendix

SCOPE OF WORK

(cont'd)

The Vendor shall work toward achieving the following goals within the assigned geographic area and will accomplish the following objectives. This will be accomplished by performing the specified activities and evaluating the results using the listed methods to focus on process and/or outcome. All activities will be carried out in accordance with the Newborn Screening regulations, protocols and procedures. During an emergency, geographic areas may be temporarily reassigned.

Goals No. 1 & 2 (Continued)

MEASURABLE OBJECTIVES	IMPLEMENTATION ACTIVITIES	TIMELINE	METHOD(S) OF EVALUATION PROCESS AND/OR OUTCOME OF OBJECTIVE(S)
<p>9. Education and training provided to those in newborn screening, i.e., physicians, hospital personnel, public health departments, midwives, etc.</p>	<p>*Assess knowledge and learning needs of target groups.</p> <p>*Design and present educational programs to address identified needs.</p> <p>*Conduct at least 6 educational programs annually and more when needed.</p> <p>*Evaluate effectiveness of educational strategies.</p>	<p>ASC Annual Plan due June 1, yearly</p> <p>on-going</p> <p>yearly</p> <p>quarterly</p>	<p>Submit to State for review and approval, an annual education/quality improvement plan which includes the following information:</p> <ul style="list-style-type: none"> - description of region's identified learning needs and respective target audiences. - methods and tools used to assess needs - objectives - plan to address needs (i.e., informal in-services, continuing education programs, newsletters, etc.) - timelines/schedule of events (dates, length of time, locations) - method of evaluation <p>Submit to State for approval at least two weeks prior to presentation, agenda, course outline, program length, targeted audience, goals and objectives, methodologies, copy of handouts, printout of slides and evaluation tools. (State supplied or approved course outlines and materials e.g., slides, do not need to be submitted unless modified.)</p> <p>Maintain ASC file with list of participants, copies of evaluations.</p> <ul style="list-style-type: none"> - HEPP reports
<p>10. Quality improvement activities are implemented to assure that NBS program objectives are met, problems are addressed or prevented, and evaluation is on-going.</p>	<p>*Develop written corrective action plans for identified problems.</p> <p>*Develop corrective action plan appropriate, when time frames are not met. Monitor key milestones in follow-up of newborns as defined by GDB (e.g., time from referral to appointment at CCS Center, time to diagnosis, time to treatment, etc.). Obtain diagnosis and treatment information from baby's physician.</p> <p>*Review Hospital Evaluation Performance Profile (HEPP) reports and distribute to facilities with ASC region.</p> <p>*Follow-up with facilities that have significant numbers of deficiencies and/or on-going deficiencies that do not decrease over time.</p> <p>*Provide on-going feedback to facilities regarding their performance and compliance with NBS regulations, policies, and protocols.</p>	<p>when appropriate</p> <p>on-going</p> <p>monthly, quarterly, and annually</p> <p>monthly, and quarterly</p> <p>on-going</p>	<p>Copies of completed corrective action plans are to be submitted to the contract liaisons in quarterly reports.</p> <ul style="list-style-type: none"> - BO reports. - HEPP reports

Appendix

SCOPE OF WORK

(cont'd)

The Vendor shall work toward achieving the following goals within the assigned geographic area and will accomplish the following objectives. This will be accomplished by performing the specified activities and evaluating the results using the listed methods to focus on process and/or outcome. All activities will be carried out in accordance with the Newborn Screening regulations, protocols and procedures. During an emergency, geographic areas may be temporarily reassigned.

Goals No. 1 & 2 (Continued)

MEASURABLE OBJECTIVES	IMPLEMENTATION ACTIVITIES	TIMELINE	METHOD(S) OF EVALUATION PROCESS AND/OR OUTCOME OF OBJECTIVE(S)
11. Provide input in the continuing development, implementation, and evaluation of the Newborn Screening Program.	*Attend Statewide meetings and in-service programs as required by the State. Attendance at other program meetings/conferences	on-going	Attendance records will be kept by the State. Maintain in ASC file. Written report, conference materials, and/or other items of significance.
	*Participate in ad hoc committees, Maternal PKU Camp, and special projects as requested.	on-going	Committee lists, meeting sign-in sheets and/or participant lists.

3.3.2. Genetic Disease Screening Program (GDSP) Administrative Policies (FY 2011–2014)

The following are administrative policies for the Genetic Disease Screening Program (GDSP) Newborn Screening Area Service Center (ASC) Vendor Agreements. Administrative requirements change from time to time, and GDSP reserves the right to adjust its policies accordingly at any time.

Exceptions to any policies must be requested in writing and approved by the State Newborn Screening Program (NBSP) ASC Vendor Agreement Liaison. Documentation of approval will be sent to the requesting party and a copy retained in the ASC Vendor Agreement file.

PERSONNEL

The percent of time listed for each position funded by the ASC Vendor Agreement must coincide with the percent of time the employee actually performs duties specific to the NBS Program ASC Vendor Agreement Scope of Work.

QUALIFICATIONS

- **Project Director/Kaiser Lead Coordinator
(minimum one full-time person)**

Registered* Nurse with at least two years of pediatric, maternal/child health, neonatal or public health experience; at least two years of experience in program planning and administration, supervision, and development and/or implementation of educational programs; bachelor's degree in nursing and master's degree in a related field

OR

Registered* Nurse with at least two years of experience as a full-time Coordinator for the California Newborn Screening Program and at least two years of experience in program planning and administration, supervision, and development and/or implementation of educational programs; bachelor's degree in nursing

- **Coordinator
(minimum one FTE if the ASC is responsible for 50,000 births/year or more)**

Registered* Nurse with at least one year of pediatric, maternal/child health, neonatal, or public health experience and bachelor's degree in nursing

OR

Other Licensed Health Professional, with bachelor's degree and with two years of experience in a state newborn screening program.

*Applicant/staff must possess an active, valid license as a registered nurse in the State of California.

- **Program Specialist**

Genetic Counselor with master's degree and with at least one year experience in a hospital inpatient or outpatient clinic setting (board certification preferred)

OR

Registered Dietician with master's degree and with at least one year experience in a hospital inpatient or outpatient clinic setting; Metabolic Clinic experience preferred

OR

Other health professional with master's degree (e.g., Social Worker, Health Education Specialist) and with a minimum of one year of experience in a state NBS program or two years of experience in pediatric, maternal/child health, or public health

OR

Other health professional with bachelor's degree and with two years of experience in a state newborn screening program

- **Community Liaison**

Social Worker, Health Educator, or other health worker with bachelor's degree and with at least one year of experience, including providing patient education

- **Administrative Assistant**

To be filled based on the ASC Project Director's and institution's administrative requirements and desired qualifications for the position.

FILLING VACANCIES

When filling vacant positions, the NBSP ASC Vendor Agreement Liaison may be consulted for assistance with job classification/title, proposed salary, recruitment plan, and/or review of the candidate's application/resume.

For the position of Project Director, the NBSP ASC Vendor Agreement Liaison must review and approve the position posting and candidate's application/resume to ensure that the applicant possesses the desired skills and qualifications, prior to the position being offered.

OFFICE COVERAGE

The Project Director, Coordinator, or Program Specialist should be present in the ASC office during normal business hours (Monday through Friday, 8:30 AM—5:00 PM), except in the event of statewide NBSP meetings for which attendance of all non-clerical ASC staff is required.

During business hours, an ASC staff person must be available to answer telephones. Messages should be picked up a minimum of every four hours.

The Project Director shall inform the NBSP ASC Vendor Agreement Liaison in advance when he/she will be out of the office for periods exceeding three days and how coverage (ASC management and clinical coverage) will be provided during that absence.

TRAVEL AND TRAINING RELATED TO SCOPE OF WORK

ASC Vendor Agreement funding covers travel for the purposes of site visits, attendance at NBSP meetings, and staff training and development to enhance knowledge and skills required to implement the NBS scope of work and to maintain professional licensure. Funding is designated for use by all ASC staff, including the Secretary. GDSP approval is not required for travel associated with NBSP activities.

OFFICE SPACE

NBSP ASC Vendor Agreement Liaison must consult on office site plans to ensure that allocated space is adequate and appropriate for the ASC staff to accomplish the activities outlined in the Scope of Work. Recommended space allowance is approximately 100 square feet/staff person. The Project Director should have a separate room/space designated for the purpose of conducting activities requiring privacy. If office space is not contiguous, the ASC offices cannot span a length greater than 250 feet.

EQUIPMENT

Technical support must be provided by the Vendor in the form of “in-house” support by their institution or in the form of a contract with an outside computer support business. The contractor is also responsible for the support and maintenance of ancillary equipment such as monitors, keyboards, and printers.

Vendor will purchase and maintain computers according to CDPH standards. Each FTE position must have a personal computer workstation and all computers used for the Newborn Screening ASC Vendor Agreement must have (at a minimum) software (Microsoft Office) and browser (Internet Explorer 8.0) as specified by state standards. These computers must have access to the ASC Vendor’s local area network e-mail, an Internet service provider for Web access, and access to the State of California Department of Public Health Genetic Disease Screening Programs Screening Information System (SIS) and Business Objects (BO).

The minimum technical specifications for computer/equipment/software are to be obtained from the NBSP ASC Vendor Agreement liaison.

Equipment purchased with funds from the Vendor Agreement becomes the property of CDPH and must be returned as requested and accounted for via Inventory/Disposition of CDPH Funded Equipment (CDPH 1203), Contract Equipment Purchased with CDPH Funds (CDPH 1204), and Physical Inventory of Accountable Equipment (CDPH 1205) forms.

REPORTS

ASC Project Director submits monthly, quarterly and annual reports related to the NBSP ASC Vendor Agreement SOW deliverables, objectives, and quality improvement plans per ASC Vendor Agreement Reporting Requirements.

PROVISION OF SERVICES

All services and procedures must be provided in accordance with the State's Newborn Screening Program Laws and Regulations, Administrative Policies, Scope of Work and Protocols. Any problems in following these procedures must be brought to the immediate attention of the state.

INVOICING

Vendor will submit a monthly invoice for payment. State staff will review invoices monthly and will utilize BO reports to assure SOW activities are implemented prior to the authorization of payment.

ALTERNATE WORK METHODS

The NBSP supports the concept of limited telecommuting at the discretion of the ASC Project Director per Vendor's Institution approved procedures. Telecommuting time must not exceed one day/week except in disaster or emergency situations.

EMERGENCY/DISASTER COVERAGE

ASC assignments may be temporarily adjusted to assure coverage to all of California hospitals and newborns during times of emergency or disaster.

PUBLIC NOTIFICATIONS

The Vendor shall acknowledge the support of the State whenever publicizing the work under this agreement in any media. This provision does not apply to necessary staff meetings or training session held for the staff of the Vendor to conduct routine business matters.

3.3.2.1. Roles & Duties of ASC Positions—General Guidelines (FY 2011–2014)

Project Director (Non-Kaiser)

- Assigns tasks (newsletters, graphs/tables, etc.) based on staff expertise
- Develops and oversees ASC budget
- Supervises, trains, and evaluates ASC staff
- Works with Human Resources Department to hire and terminate staff
- Assumes responsibility for vendor agreement deliverables, i.e., ensures that Newborn Screening Program ASC Vendor Agreement Scope of Work is carried out, that administrative policies are followed, and that terms of Area Service Center vendor agreement are met
- Provides reports to Genetic Disease Screening Program, as required
- Develops and/or approves curricula for training of NBS providers
- Develops/ implements quality assurance and improvement mechanisms that are used for ongoing evaluation of NBS providers and ASC
- Provides backup to staff for follow-up activities
- Facilitates and oversees planning process for ASC
- Provides consultation and technical assistance to NBS providers, physicians, etc.

Lead NBS Coordinator (Kaiser)

- Performs all duties of NBS Coordinator
- Assumes responsibility for day-to-day completion of SOW
- Provides reports to Genetic Disease Screening Program, as required
- Develops and/or approves curricula for training of ASC staff, NBS providers
- Facilitates and oversees planning process for ASC
- Develops/ implements quality assurance and improvement mechanisms that are used for ongoing evaluation of NBS providers and ASC
- Coordinates the assignment of special tasks (development of newsletters, graphs/tables, etc.) based on staff expertise

NBS Coordinator

- Calls out and tracks all complex positives; facilitates referrals for parents to physician offices, clinics, CCS Special Care Centers, or CCS-paneled specialists
- Handles all post-transfusion follow-up for those babies who have other positives on their screen
- Handles all NICU “Inadequates” and “Earlies”
- Provides consultation and technical assistance to NBS providers, physicians, etc.
- Functions as team leader for site visits and in-service training sessions
- Clinical resource for NBS Program Specialist on call outs of non-NICU positives
- Assists with annual planning process and implementation of plan
- Primary contact for hospitals in the region as assigned by Project Director:
 1. Reviews reports like BO and HEPP and evaluates needs of assigned hospitals for in-services and site visits
 2. Coordinates all development/educational needs for assigned hospitals
 3. Develops corrective action plans (CAPs) for assigned hospitals, as needed

NBS Program Specialist

- Calls out and tracks routine/non-complex positives; facilitates referrals for parents to physician offices, clinics, CCS Special Care Centers, or paneled specialists
- May assist with weekend call at discretion of Project Director/Lead Coordinator with back up of NBS Coordinator, Project Director or NBS Medical Consultant
- Handles all post-transfusion follow-up for those babies who have no other positive involved in their screen
- Functions as back up to Community Liaison for non-NICU “Inadequates” and “Earlies”
- Participates on site-visit teams
- Identifies and evaluates Web sites and other educational materials for families; coordinates reviews of educational materials with GDSP health educators
- Assists with HEPPs/tracking of hospital deficiencies, etc.
- Assists with OHs, NOs, and MRs
- Provides consultation and technical assistance regarding NBS program and processes to NBS providers, physicians, etc.
- Assists with annual planning process and implementation of plan

Community Liaison

- Handles and tracks all non-NICU “Inadequates” and “Earlies”
- Handles NOs, OHs, MRs
- Monitors hospitals for inadequate/early trends and suggests interventions to address
- Coordinates and participates in community outreach activities, health fairs, etc.
- Develops and maintains community resources/information for families (e.g., transportation, assistance with payment sources, resources for other psychosocial needs)
- Participates on site-visit teams
- Assists with CCS paperwork, as requested
- Functions as liaison to clinics, physician offices, etc. to expedite visits and makes appointments for families when requested.
- Provides consultation and technical assistance to NBS providers, physicians, etc.
- Assists with annual planning process and implementation of plan

Secretary/Administrative Assistant

- Handles general clerical duties and correspondence for ASC
- Answers ASC phones
- Maintains supplies and educational materials
- Schedules and maintains calendar of site visits/in-services.
- Maintains NBS statistics and data.

Project Director/Medical Consultant (Kaiser)

- Provides clinical consultation and technical assistance on newborn screening follow-up to NBSP ASC staff and to the medical community
- Meets regularly (at least monthly) with ASC staff and additionally, as needed, to review follow-up procedures and complex cases
- Conducts presentations (e.g., grand rounds) on newborn screening to medical community, upon request, and attends meetings (as needed) of targeted groups of physicians to educate them on newborn screening issues.
- Represents ASC and Newborn Screening Program in agency/institution’s pediatrics department
- Attends state Newborn Screening Program meetings, as requested

- Collaborates with ASC Project Director/lead coordinator, when needed, in obtaining needed resources in agency (e.g., expediting posting/recruitment of ASC positions by Human Resources Department)
- Assumes responsibility for vendor agreement deliverables, i.e., ensures that the Newborn Screening ASC Scope of Work is carried out, that administrative policies are followed, and that terms of Area Service Center vendor agreement are met
- Reviews and signs quarterly and annual reports
- Reviews and signs all reports to approve personnel changes and requests for training and related travel

Medical Consultant (Non-Kaiser)

- Provides clinical consultation and technical assistance on newborn screening follow-up to NBSP ASC staff and to the medical community
- Meets regularly (at least monthly) with ASC staff and additionally, as needed, to review follow-up procedures and complex cases
- Conducts presentations (e.g., grand rounds) on newborn screening to medical community, upon request, and attends meetings (as needed) of targeted groups of physicians to educate them on newborn screening issues
- Represents ASC and Newborn Screening Program in agency/institution's pediatrics department
- Attends state Newborn Screening Program meetings, as requested
- Collaborates with ASC Project Director/lead coordinator, when needed, in obtaining needed resources in agency (e.g., expediting posting/recruitment of ASC positions by Human Resources Department)
- Reviews and signs annual reports

3.3.3. NBS ASC Vendor Agreement Reporting Requirements (Exhibit A— Attachment 1 of Vendor Agreement) (FY 2011–2014)

The purpose of the following reports is to keep the Newborn Screening Program informed of ASCs' activities in carrying out the SOW in compliance with the contract. Reports are due to the NBS Program Vendor Agreement Liaison by the dates shown.

ASC ANNUAL PLAN—Due June 1 for the fiscal year beginning July 1.

1. Signed Progress Report Form (See 3.3.3.1)
2. Annual Quality Improvement Plan (See 3.3.3.2)
3. Annual Staffing Plan and ASC Budget
4. Annual Hospital Monitoring Log - Lists all hospitals in region (showing visit plans for the next fy, monthly HEPPs for past “rolling” year, all completed site visit dates for the last 2 rolling years, and all completed inservice dates for the last 2 rolling years).
5. Annual Contractor Equipment Purchased With CDPH Funds Form 1203
6. Annual Inventory/Disposition of CDPH- Funded Equipment Form 1204
7. Annual Physical Inventory of Accountable Equipment Form 1205
8. List of specialist consultants used by the ASC as a resource and to whom other physicians with specialty questions are referred.

ASC MONTHLY REPORT—Due by the 15th of each month

GDSP and ASC's will run selected BO reports monthly

ASC reports on:

Problematic Cases or Issues

Explanation of data reported outside normal timelines.

List of Site Visits completed, Institution, # Attendees, Staff and Dates;

List of In-services completed, Institution, Dept., # Attendees, Staff, Dates

NBS Related Training/ Travel completed, Location, Dates, Staff;

Staffing schedules for next month (time off vacations etc.);

Staffing schedules for next month weekend call.

ASC QUARTERLY REPORT—Due 21 days after the end of each quarter—to be submitted by the 21st of October (Q1), January (Q2), April (Q3), and July (Q4)

1. **Signed Progress Report Form** (See 3.3.3.1)
2. **Report of staff orientation and training activities completed**
3. **Progress report on SOW Goals and Objectives**
4. **Quality Improvement Plan Progress Report** (from the QI Work Plan)—(should include a status report for each objective (i.e., planned actions taken or completed, results and progress toward meeting objectives, problems encountered in implementation, any changes or modifications of the planned activities, and/or added objectives. **Objectives cannot be eliminated during the year.**
5. **Corrective Action Plan (CAP) Log and CAPs** in progress or completed. A QI/corrective action plan should be included for each hospital with greater than 3 monthly HEPP reports in the last “rolling” year.

The following items do not require submission with reports but must be maintained on file at the ASC and readily available for review during NBS ASC Vendor Agreement Liaison Site Visits to the ASC

- ✓ Assessment tools utilized (surveys, questionnaires, etc.). Must submit in advance for NBS approval.
- ✓ Final printed versions of state-approved newsletters or mass mailings completed during the quarter.
- ✓ Site Visit/In-Service Log - Materials from new in-services/presentations must be submitted to contract liaison for approval **two weeks** prior to the presentation (See Objective #8 of SOW). Maintain with the Log:
 - Completed *Training Form* and outline for each in-service presentation.
 - Completed evaluation forms or summary of evaluations for each in-service and site visit.
 - Attendance/sign-in lists for each in-service and site visit.

ASC YEAR-END SUMMARY—Due July 31 for previous fiscal year

1. Signed Progress Report Form (See 3.3.3.1)
2. Final report of Quality Improvement Plan for the previous year.
3. Director’s/Kaiser Lead Coordinator’s report and recommendations.

ASC MONTHLY REPORT

ASC: _____ Date of Report: _____ Month of: _____

Workload Issues (trends & efforts to improve):

1. **Problematic Cases or Issues**
2. **Explanation of data reported outside normal timelines**
3. **Other**

Site Visits: # Scheduled: _____ # Completed: _____

Site Visits – Hospital Name	Date of Visit	# Attended	Staff Attended

In-Services: # Scheduled: _____ # Completed: _____

Hospital Name and Dept.	Date of Visit	# Attended	Staff Attended

NBS Related Training/Travel/Meetings Attended:

Meeting/Place	Dates	Staff Attended	Agenda/Issues Discussed

Staffing Schedules for Next Month (Extended time off/ vacations etc.):

Name	Dates	Name	Dates

Staffing Schedules for Next Month (Weekend call):

Name	Dates	Name	Dates

Questions/Pending Issues from GDSP Liaison:

ASC QUARTERLY REPORT

ASC: _____ Date of Report: _____ Quarter: _____

Attach a Signed Copy of Progress Report Form (Exhibit A—Attachment II).

ASC New Staff Orientation/Training Completed

Topics	Staff	Status

Scope of Work Progress Report

Cite issues/concerns or accomplishments pertaining to any SOW goals or objectives

Goal/Objective#	Report of Progress/Concerns

Corrective Action Plans (CAPS) completed or in progress

Corrective action plan should be included for each hospital with greater than 3 monthly HEPP reports in the last “rolling” year or other situations in which a CAP was completed.

CAP – Hospital Name	Reason for CAP	Date Completed

Quarterly Quality Improvement Plan Progress Report

See next page

ASC Annual Quality Improvement Plan and Quarterly Report
FY _____

Select at least two identified problems on which the ASC will focus.

Use this format for each problem.

Objective # _____

(Be specific and measurable and include numerical target you expect to reach by end of FY):

Assessment

(What is the scope of the problem? How did you identify this problem?):

Target Group: _____

Action Plan/Interventions Responsible person(s)	Timeline/Expected Dates for Intervention (When plan activities will be carried out)	Method(s) of Evaluation (How will you measure if objective is being met)

Quarterly Quality Improvement Plan Progress Report

Report for each objective (i.e., actions taken or completed, identify results and progress toward meeting targets, problems encountered in implementation, any changes or modifications of the planned activities, and/or added objectives.

Objectives cannot be eliminated during the year.

Quarter 1 Progress Report:

Quarter 2 Progress Report:

Quarter 3 Progress Report:

Quarter 4 Progress Report:

3.3.3.1. Progress Report Signature Form

PROGRESS REPORT SIGNATURE FORM

*Submit original of completed report to:
California Department of Public Health
Genetic Disease Screening Program
850 Marina Bay Pkwy, F175
Richmond, CA 94804*

1. REPORT PERIOD:

- | | | |
|--------------------------|-------------------------|---|
| <input type="checkbox"/> | ASC Annual Plan | Submit by June 1 for the fiscal year beginning July 1 |
| <input type="checkbox"/> | First Quarterly Report | July 1 - Sept. 30 submit by Oct. 21 |
| <input type="checkbox"/> | Second Quarterly Report | Oct. 1 - Dec. 31 submit by Jan. 21 |
| <input type="checkbox"/> | Third Quarterly Report | Jan. 1 - March 31 submit by April 21 |
| <input type="checkbox"/> | Fourth Quarterly Report | April 1 - June 30 submit by July 21 |
| <input type="checkbox"/> | ASC Year End Summary | Submit by July 31 for the previous fiscal year |

2. CONTRACT NUMBER:**3. PROJECT TITLE:****4. AGENCY NAME AND ADDRESS:****5. REPORT PREPARED BY:**

NAME:
TITLE:
PHONE:

INSTRUCTIONS

- A. Complete reports using the formats provided by the State.
- B. Summarize progress made to date toward meeting the objective. Use quantifiable terms if applicable. This should include a brief summary of both implementation and evaluation activities.
- C. Briefly describe any problems encountered in implementing an objective. Outline strategies for dealing with any unresolved problems. Discuss personnel transactions (including vacancies) which have had an impact on meeting an objective.
- D. Address any issues needing the special attention of State staff.

CERTIFICATION OF PROJECT DIRECTOR/KAISER LEAD COORDINATOR

I affirm that the information present in this report accurately reflects the current status of this project to the best of my knowledge.

Original Signature:

Date:

(Project Director/Lead Coordinator)

3.3.3.2. ASC Annual Quality Improvement Plan

ASC Annual Quality Improvement Plan: **FY**_____

Select at least two identified problems on which the ASC will focus.

Use this format for each problem.

Objective # _____

(Be specific and measurable and include numerical target you expect to reach by end of FY):

Assessment

(What is the scope of the problem? How did you identify this problem?):

Target Group: _____

Action Plan/Interventions Responsible person(s)	Timeline/Expected Dates for Intervention (When plan activities will be carried out)	Method(s) of Evaluation (How will you measure if objective is being met)

3.3.3.3. Site Visit/In-Service Log

SITE VISIT/IN-SERVICE LOG

- Materials from new in-services/presentations must be submitted to contract liaison for approval **two weeks** prior to the presentation (See Objective #8 of SOW).
- Attach the following to the Log:
 - Completed *Training Form* and outline for each in-service presentation.
 - Completed evaluation forms or summary of evaluations received for each in-service and site visit.

Facility/Hospital	SV/IN	ASC Staff Attending	Title of In-Service/ Site Visit Issues Discussed	Recommendations/Next Steps

g/nbs/ASC Initl, Qtrly, Mo. Rpts./Site Visit_Ins.Log 3-21-06

3.3.3.4. Corrective Action Plan (CAP)

CORRECTIVE ACTION PLAN (CAP)

Facility _____

Quarter _____

PROBLEM	ACTION	TARGET DATE(S)	EVALUATION
	<p>List what actions will be taken at your facility to address/correct the indicated deficiencies.</p>	<p>Add your facility target date.</p>	<p>Add your facility evaluation criteria.</p>

Date: _____ Hospital/Facility Representative/Responsible Person

NBS Project Director or Coordinator

(Name)

(Name)

(Title)

(Title)

g/nbs/ASC Initl,Qtrly, Mo. Rpts/CORRECTIVE ACTION PLAN 11-6-05

3.4.1. Metabolic Center Vendor Agreement and Scope of Work (SOW)

Vendor's Name
11-MCXXX

1. Service Overview

Vendor agrees to provide to the California Department of Public Health (CDPH) the services described herein.

The Vendor must be a California Children's Services (CCS) approved Metabolic Special Care Center providing multidisciplinary care at the clinic site. CCS approval must be maintained throughout the term of the agreement.

The Vendor shall provide a timely diagnosis for cases referred by the CDPH, Genetic Disease Screening Program (GDSP) Newborn Screening Program (NBSP) to prevent morbidity or mortality associated with the metabolic disorder as well as document the referral and diagnostic decision into the GDSP Screening Information System (SIS). **Infants to be referred to the Vendor include those who test positive for Galactosemia and over forty conditions, including Phenylketonuria (PKU), detectable via tandem mass spectrometry (MS/MS) and biotinidase deficiency (See Exhibit A: Attachment I).**

The acceptance of this Agreement certifies that services provided by the Vendor will comply with GDSP program policies, guidelines, and protocols for the California Newborn Screening Program. It also certifies that services provided meet national treatment guidelines as appropriate to California.

2. Service Location

The services shall be performed at clinic locations and any CCS-approved satellite clinics.

3. Service Hours

The services shall be provided during normal Vendor working days and hours, and arrangements made for on-call coverage during non-business hours.

4. Project Representatives

a. The project representatives during the term of this Agreement will be:

California Department of Public Health Administrator Muslimah Jaavaid Telephone: (510) 412-1476 Fax: (510) 412-1548 Email: MJavaaid@cdph.ca.gov	Vendor's Name Agency Official {Enter name of Vendor's Contract Mgr.) Telephone: (XXX) XXX-XXXX Fax: (XXX) XXX-XXXX Email: XXXXXXXX@XXXX.XXX
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- b. Direct all inquiries to

California Department of Public Health NBSB Metabolic Center Liaison Genetic Disease Screening Program Attention: Carole Klein, MPH Mail Station Code 8200 850 Marina Bay Parkway Richmond, CA 94804 Telephone: (510) 412-1481 Fax: (510) 412-4657 Email: Carole.Klein@cdph.ca.gov	Vendor's Name Project Director Section or Unit Name (if applicable) Attention: (Enter Name) Street Address & room number P.O. Box Number (if applicable) City, State, Zip Code Telephone: (XXX) XXX-XXXX Fax: (XXX) XXX-XXXX Email: XXXXXXXX@XXXX.XXX
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- c. Either party may make changes to the information above by giving written notice to the other party. Said changes shall not require an amendment to this Agreement.

5. Services to be Performed

Vendor shall perform the following services:

- a. Enter into SIS the short-term and long-term reportable data on the referred and diagnosed newborn cases. Reportable data encompasses information related to the consultation with the newborn's Primary Medical Doctor (PMD), Newborn Screening Area Service Centers (ASCs), and the NBSP staff regarding cases referred to the Metabolic Center with a positive newborn screening result, as well as providing clinical information to GDSP on conditions screened for by the California NBSP.
- b. Participate in periodic meetings convened and funded by the NBSP to review and consult on the effectiveness of newborn screening, reference ranges, patterns and reporting of results, and follow-up protocols.

- c. Contact the PMD to discuss health status of referred newborns and determine whether it is necessary for the baby to be seen immediately by a specialist. Communicate by telephone, secure fax, or e-mail with PMD, as needed, regarding the status and treatment of the baby.
- d. Respond to ASC or NBSP staff requests for information on referred cases within two (2) business days of request.
- e. Upon request, provide consultation to NBSP staff, ASC staff, newborn's PMD, and/or CCS authorizing agency regarding diagnosis and treatment of metabolic conditions screened for by the GDSP.
- f. SIS Documentation

Using the GDSP Web-based SIS, provide timely documentation of significant contacts pertaining to a referred infant. New cases will appear in the top grid of the SIS Follow-Up Center Cases Referred screen. After follow-up consultation activities have been initiated and documented on a SIS Metabolic Service Report indicating that the case has been received at the Metabolic Center, the case will move to the "PENDING" grid. Once a diagnosis is confirmed or ruled out, the case will move to the third grid, "RESOLVED CASES."

SIS Metabolic Service Report

The online SIS Metabolic Services Report form (MSR) is a mechanism for documenting significant contacts made regarding a referred infant from the time of initial referral until the diagnostic decision is made and any necessary treatment is initiated. The information gained from the MSR is used by the GDSP to evaluate the effectiveness of the screening program. It is important that the Metabolic Center enter information into all the fields of the MSR form, including the Health Profile. An MSR should be completed for significant contacts. This data includes physician telephone consultations, contact with the family in person or by telephone, the initial clinic visit, other physician consultations, and follow-up visits for diagnostic evaluation. The final MSR shall document the diagnostic decision and information on the treatment initiated.

The SIS MSR shall be completed as **soon as possible preferably within one (1) business day but no later than five (5) calendar days** of each significant contact and the diagnostic decision. After a diagnosis is confirmed or ruled out, treatment (if indicated) initiated, and this information entered in an MSR, further MSRs are no longer required for that patient.

SIS Genotype Entry

If genotyping or mutation analysis results are available, enter these results in the Confirmatory Test Results section of SIS by selecting "DNA" as the Test Type.

SIS Case Notes

After entering the MSR, Case Notes may be added when additional information is needed to augment or clarify that MSR—for example, when the contact type checked on the MSR is “Other,” for brief explanations, for unusual delays in diagnosis, or for estimate of time until confirmatory results will be available. Other reasons for Case Notes include notes about the date of the next appointment, additional testing ordered, or case status since the last MSR. However, **Case Notes do not replace the need for an MSR when a significant contact is made that provides information about the referred NBS case.**

For a diagnosis taking more than a month, the Center should communicate at least monthly with the ASC regarding the case status. The Center can discuss with the ASC the best way to communicate updates, using one or more modes of contact: e-mail, telephone, or SIS Case Notes.

SIS Metabolic Center Annual Patient Summary

A SIS Metabolic Center Annual Patient Summary (MCAPS) must be completed in SIS once a year for each child diagnosed with a metabolic disorder for which GDSP screens until the child is five years of age. Each month, Metabolic Centers will receive a list in SIS of referred cases of children who had a birthday in the previous month who are due to have an MCAPS. The MCAPS should be completed by the end of the following month (the month after the child’s birthday). Guidelines for completing the MCAPS can be found in the Data Entry Manual. Any questions about SIS and completing the MSRs or the MCAPS should be directed to the Metabolic Center Vendor Liaison.

Some metabolic cases taking more than 6 months to resolve at the Metabolic Center will be followed directly by staff at the GDSP. Metabolic Centers will be contacted directly by GDSP staff concerning extended case follow-up and given instructions about any additional information that is needed. MSRs still need to be kept current on these cases until they are resolved.

- g. Notify the GDSP by telephone or email each time a new diagnosis of a metabolic disorder for which NBSP screens is made at your Center for a patient who was **screened but not identified as *Screen Positive* by the California NBSP, regardless of patient age.**
- h. Notify the GDSP by telephone or e-mail each time a new diagnosis of a metabolic disorder for which NBSP screens is made at your Center for a patient up to 5 years of age, who was **not screened by the California NBSP**. Provide information on name, birthdate, demographic characteristics, and the results of confirmatory testing. Within five (5) days, Center shall complete pertinent information on the MSR screen in SIS on encounters with each new patient who was not initially screened by GDSP, up to the point of diagnosis and initiation of

treatment. Centers also shall complete a SIS MCAPS once a year on each of these new patients until the child is 5 years of age.

- i. The NBSP Metabolic Center Vendor Liaison must be notified regarding any changes in the Metabolic Center core clinic team members or staff who will be entering information into SIS.

6. Reimbursement

The GDSP shall reimburse the Vendor, using a unit-cost methodology, for each new case referred and for each annual follow-up for diagnosed cases, as reported in SIS. See Exhibit B, for a detailed outline of the rate payable schedule. GDSP will provide a report quarterly that contains the number of new referrals and completed Annual Patient Summaries to be used in completing the invoice for the associated time period.

7. Representation and Participation

The Vendor shall release staff specified by the NBSP to attend regional or statewide meetings planned and convened by the NBSP, i.e., statewide planning meetings, guideline subcommittees, Maternal Phenylketonuria Camp, (MPKU Camp), etc. Vendor staff shall assist the GDSP in the further development of the NBSP by recommending and responding to proposed policy changes and providing information as requested.

8. Confidential and Privileged Information

The Vendor shall protect all confidential or privileged information provided by the NBSP. The confidentiality of patient files and records shall be protected by the Vendor in accordance with existing State and Federal laws and regulations.

Confidential or privileged information includes, but is not limited to, any and all information, instructions, calculations, tables, graphs, programming instructions, software, computer discs, and any other materials designated by the NBSP. The Vendor shall ensure that all personnel, including vendors, shall not release any such information to unauthorized persons except as required by law. Such information is not to be used for private gain or profit. The Vendor agrees to notify the NBSP in the event any confidential and privileged information is released without proper authorization. The Vendor agrees to reimburse the NBSP for the costs of enforcing this clause, including any legal fees.

9. Allowable Informal Scope of Work Changes

- a. The Vendor or the State may propose informal changes or revisions to the activities, tasks, deliverables and/or performance time frames specified in the

- Scope of Work, provided such changes do not alter the overall goals and basic purpose of the agreement.
- b. Informal SOW changes may include the substitution of specified activities or tasks, the alteration or substitution of agreement deliverables, and modifications to anticipated completion/target dates.
 - c. The informal change does not result in an increase or decrease to annual costs under the Agreement.
 - d. Unless otherwise stipulated in this agreement, all informal SOW changes and revisions are subject to prior written approval by the State and the vendor.
 - e. In implementing this provision, the State may provide a format for the Vendor's use to request informal SOW changes. If no format is provided by the State, the Vendor may devise its own format for this purpose.

3.4.2. Endocrine Center Vendor Agreement and Scope of Work (SOW)

Vendor's Name
11-ECXXX

1. Service Overview

Vendor agrees to provide to the California Department of Public Health (CDPH) the services described herein.

Vendor must be a California Children's Services (CCS) approved Endocrine Special Care Center providing multidisciplinary care at the clinic site. CCS approval must be maintained throughout the term of the agreement.

Vendor shall provide a timely diagnosis for cases referred by the CDPH, Genetic Disease Screening Program (GDSP) Newborn Screening Program (NBSP) to prevent morbidity or mortality associated with an endocrine disorder for which NBSP screens as well as to document the referral and diagnostic decision into the GDSP Screening Information System (SIS). **Infants to be referred include those who test positive for Congenital Adrenal Hyperplasia and Primary Congenital Hypothyroidism (see Attachment I).**

The acceptance of this Agreement certifies that services provided by the Vendor will comply with GDSP program policies, guidelines, and protocols for the California Newborn Screening Program. It also certifies that services provided meet national treatment guidelines as appropriate to California.

2. Service Location

The services shall be performed at clinic locations and any CCS-approved satellite clinics.

3. Service Hours

The services shall be provided during normal Vendor working days and hours, and arrangements shall be made for on-call coverage during non-business hours.

4. Project Representatives

- a. The project representatives during the term of this Agreement will be:

California Department of Public Health Administrator Janice Byers Telephone: (510) 412-5851 Fax: (510) 412-1548 Email: janice.byers@cdph.ca.gov	Vendor's Name Agency Official {Enter name of Vendor's Contract Mgr.) Telephone: (XXX) XXX-XXXX Fax: (XXX) XXX-XXXX Email: xxxxxxxx@xxxx.xxx
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- b. Direct all inquiries to

California Department of Public Health NBSP Endocrine Center Liaison Genetic Disease Screening Program Attention: Shellye Lessing Mail Station Code 8200 850 Marina Bay Parkway Richmond, CA 94804 Telephone: (510) 412-1487 Fax: (510) 412-4657 Email: shellye.lessing@cdph.ca.gov	Vendor's Name Project Director Section or Unit Name (if applicable) Attention: (Enter Name) Street Address & room number P.O. Box Number (if applicable) City, State, Zip Code Telephone: (XXX) XXX-XXXX Fax: (XXX) XXX-XXXX Email: xxxxxxxx@xxxx.xxx
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- c. Either party may make changes to the information above by giving written notice to the other party. Said changes shall not require an amendment to this Agreement.

5. Services to be Performed

Vendor shall perform the following services:

- a. Enter into SIS the short-term and long-term reportable data on the referred and diagnosed newborn cases. Reportable data encompasses information related to the consultation with the newborn's Primary Medical Doctor (PMD), Newborn Screening Area Service Centers (ASCs), and the NBSP staff regarding cases referred to the Endocrine Center with a positive newborn screening result, as well as providing clinical information to GDSP on conditions screened for by the California NBSP.
- b. Participate in periodic meetings convened and funded by the NBSP to review and consult on the effectiveness of newborn screening, reference ranges, patterns and reporting of results, and follow-up protocols.

- c. Contact the PMD to discuss health status of referred newborns and determine whether it is necessary for the baby to be seen immediately by a specialist. Communicate by telephone, secure fax, or e-mail with PMD, as needed, regarding the status and treatment of the baby.
- d. Respond to ASC or NBSP staff requests for information on referred cases within two (2) business days of request.
- e. Upon request, provide consultation to NBSP staff, ASC staff, newborn's PMD, and/or CCS-authorizing agency regarding diagnosis and treatment of Endocrine conditions screened for by the GDSP.
- f. SIS Documentation

Using the GDSP Web-based SIS, provide timely documentation of significant contacts pertaining to a referred infant. New cases will appear in the top grid of the SIS Follow-Up Center Cases Referred screen. After follow-up consultation activities have been initiated and documented on a SIS Endocrine Service Report indicating that the case has been received at the Endocrine Center, the case will move to the "PENDING" grid. Once a diagnosis is confirmed or ruled out, the case will move to the third grid, "RESOLVED CASES."

SIS Endocrine Service Report

The online SIS Endocrine Services Report form (ESR) is a mechanism for documenting the referral and diagnostic decision. The information gained from the ESR is used by the Genetic Disease Screening Program to evaluate the effectiveness of the screening program. It is important that the Endocrine Center enter information into all the fields of the ESR. An ESR should be completed for the initiation of the referral and when a diagnostic decision has been reached. The second and final ESR documents the diagnostic decision and information on treatment initiated.

The SIS ESR shall be completed as **soon as possible, preferably within one (1) business day but no later than five (5) calendar days** of initiation of the referral and the diagnostic decision. After a diagnosis is confirmed or ruled out, treatment (if indicated) initiated, and this information entered in an ESR, further ESRs are no longer required for that patient.

SIS Genotype Entry

If genotyping or mutation analysis results are available, enter these results in the Confirmatory Test Results section of SIS by selecting "DNA" as the Test Type.

SIS Case Notes

After completing the ESR, Case Notes may be added when additional Information is needed to augment or clarify that ESR—for example, when the contact type checked on the ESR is “Other,” for brief explanations for unusual delays in diagnosis, or for estimate of time until confirmatory results will be available. Other reasons for Case Notes include notes about the date of the next appointment, additional testing ordered, or case status since the last ESR. However, **Case Notes do not replace the need for an ESR when a significant contact is made that provides information about the referred NBS case.**

For a diagnosis taking more than a month, the Center should communicate at least monthly with the ASC regarding the case status. The Center can discuss with the ASC the best way to communicate updates, using one or more modes of contact: e-mail, telephone, or SIS Case Notes.

SIS Endocrine Center Annual Patient Summary

A SIS Endocrine Center Annual Patient Summary (ECAPS) must be completed in SIS once a year for each child diagnosed with an endocrine disorder for which California NBSP screens until the child is five years of age. Each month, Endocrine Centers will receive a list in SIS of referred cases of children who had a birthday in the previous month who are due to have an ECAPS. The ECAPS should be completed by the end of the following month (the month after the child’s birthday). Guidelines for completing the ECAPS can be found in the Data Entry Manual. Any questions about SIS and completing the ESRs or the Annual Patient Summary should be directed to the Endocrine Center Vendor Liaison.

- g. Notify the GDSP by telephone or email each time a new diagnosis of an endocrine disorder for which NBSP screens is made at your Center for a patient who was **screened but not identified as *Screen Positive* by the California NBSP, regardless of patient age.**
- h. Notify the GDSP by telephone or email each time a new diagnosis of an endocrine disorder for which NBSP screens is made at your Center for a patient up to 5 years of age, who was **not screened by the California NBSP.** Provide information on name, birthdate, demographic characteristics, and the results of confirmatory testing. Within five (5) days, Center shall complete pertinent information on the ESR screen in SIS on encounters with each new patient who was not initially screened by GDSP, up to the point of diagnosis and initiation of treatment. Centers also shall complete a SIS ECAPS once a year on each of these new patients until the child is 5 years of age.

- i. The NBSP Endocrine Center Vendor Liaison must be notified regarding any changes in the Endocrine Center core clinic team members or staff who will be entering information into SIS.

6. Reimbursement

The GDSP shall reimburse the Vendor, using a unit-cost methodology, for each new case referred and for each annual follow-up for diagnosed cases as reported in SIS. See Exhibit B for a detailed outline of the rate payable schedule. GDSP will provide a report quarterly that contains the number of new referrals and completed Annual Patient Summaries to be used in completing the invoice for the associated time period.

7. Representation and Participation

The Vendor shall release staff specified by the NBSP to attend regional or statewide meetings planned and convened by the NBSP, i.e., statewide planning meetings, guideline subcommittees, etc. Vendor staff shall assist the GDSP in the further development of the NBSP by recommending and responding to proposed policy changes and providing information as requested.

8. Confidential and Privileged Information

The Vendor shall protect all confidential or privileged information provided by the NBSP. The confidentiality of patient files and records shall be protected by the Vendor in accordance with existing State and Federal laws and regulations.

Confidential or privileged information includes, but is not limited to, any and all information, instructions, calculations, tables, graphs, programming instructions, software, computer discs, and any other materials designated by the NBSP. The Vendor shall ensure that all personnel, including vendors, shall not release any such information to unauthorized persons except as required by law. Such information is not to be used for private gain or profit. The Vendor agrees to notify the NBSP in the event any confidential or privileged information is released without proper authorization. The Vendor agrees to reimburse the NBSP for the costs of enforcing this clause, including any legal fees.

9. Allowable Informal Scope of Work Changes

- a. The Vendor or the State may propose informal changes or revisions to the activities, tasks, deliverables and/or performance time frames specified in the Scope of Work, provided such changes do not alter the overall goals and basic purpose of the agreement. Such informal changes shall not require a formal amendment to the agreement.

- b. Informal SOW changes may include the substitution of specified activities or tasks, the alteration or substitution of agreement deliverables, and modifications to anticipated completion/target dates.
- c. The informal change shall not result in an increase or decrease to annual costs under the Agreement.
- d. Unless otherwise stipulated in this agreement, all informal SOW changes and revisions are subject to prior written approval by the State and the Vendor.
- e. In implementing this provision, the State may provide a format for the Vendor's use to request informal SOW changes. If no format is provided by the State, the Vendor may devise its own format for this purpose.

3.4.3. Hemoglobin Center Vendor Agreement and Scope of Work (SOW)

Vendor's Name
11-SCCXXX

1. Service Overview

Vendor agrees to provide to the California Department of Public Health (CDPH) the services described herein.

Vendor must be a California Children's Services (CCS) approved Sickle Cell Disease Special Care Center providing multidisciplinary care at the clinic site. CCS approval must be maintained throughout the term of this Agreement.

Vendor shall provide a timely diagnosis for cases referred by the CDPH, Genetic Disease Screening Program (GDSP) Newborn Screening Program (NBSP) to prevent morbidity or mortality associated with a hemoglobin disorder for which NBSP screens as well as to document the referral and diagnostic decision into the GDSP Screening Information System (SIS). **Infants to be referred include those who test positive for hemoglobinopathies (see Attachment I).**

The acceptance of this Agreement certifies that services provided by the Vendor will comply with GDSP program policies, guidelines, and protocols for the California Newborn Screening Program. It also certifies that services provided meet national treatment guidelines as appropriate to California.

2. Service Location

The services shall be performed at clinic locations and any CCS-approved satellite clinics.

3. Service Hours

The services shall be provided during normal Vendor working days and hours, and arrangements shall be made for on-call coverage during non-business hours.

Project Representatives

- a. The project representatives during the term of this Agreement will be

<p>California Department of Public Health Administrator Telephone: Fax: Email:</p>	<p>Vendor Agency Official [Enter Name of Vendor’s Contract Manager] Telephone: (XXX) XXX-XXXX Fax: (XXX) XXX-XXXX Email: XXXXXXXX@XXXXXXX</p>
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- b. Direct all inquiries to

<p>California Department of Public Health NBSP Sickle Cell Disease Center Liaison Genetic Disease Screening Program Attention: Carole Klein, MPH Mail Station Code 8200 850 Marina Bay Parkway Richmond, CA 94804 Telephone: (510) 412-1481 Fax: (510) 412-4657 Email: carole.klein@cdph.ca.gov</p>	<p>Vendor Project Director Section or Unit Name (if applicable) Attention: [Enter name, if applicable] Street address & room number, if applicable P.O. Box Number (if applicable) City, State, Zip Code Telephone: (XXX) XXX-XXXX Fax: (XXX) XXX-XXXX Email: XXXXXXXX@XXXXXXX</p>
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- c. Either party may make changes to the information above by giving written notice to the other party. Said changes shall not require an amendment to this Agreement.

4. Services to be Performed

Vendor shall perform the following services:

- a. Enter into SIS the short-term and long-term reportable data on the referred and diagnosed newborn cases. Reportable data encompasses information related to the consultation with the newborn’s Primary Medical Doctor (PMD), Newborn Screening Area Service Centers (ASCs), and the NBSP staff regarding cases referred to the Sickle Cell Disease Center with a positive newborn screening result, as well as providing clinical information to GDSP on conditions screened for by the California NBSP.
- b. Participate in periodic meetings convened and funded by the NBSP to review and consult on the effectiveness of newborn screening, reference ranges, patterns and reporting of results, and follow-up protocols.

- c. Contact the PMD to discuss health status of referred newborns and determine whether it is necessary for the baby to be seen immediately by a specialist. Communicate by telephone, secure fax, or e-mail with PMD, as needed, regarding the status and treatment of the baby.
- d. Respond to ASC or NBSP staff requests for information on referred cases within two (2) business days of request.
- e. Upon request, provide consultation to NBSP staff, ASC staff, newborn's PMD, and/or CCS-authorizing agency regarding diagnosis and treatment of hemoglobin conditions screened for by the GDSP.
- f. SIS Documentation

Using the GDSP Web-based SIS, provide timely documentation of significant contacts pertaining to a referred infant. New cases will appear in the top grid of the SIS Follow-Up Center Cases Referred screen. After follow-up consultation activities have been initiated and documented on a SIS Hemoglobin Service Report indicating that the case has been received at the Sickle Cell Disease Center, the case will move to the "PENDING" grid. Once a diagnosis is confirmed or ruled out, the case will move to the third grid, "RESOLVED CASES."

SIS Hemoglobin Service Report

The online SIS Hemoglobin Service Report form (HSR) is a mechanism for documenting significant contacts made regarding a referred infant from the time of initial referral until the diagnostic decision is made and any necessary treatment is initiated. The information gained from the HSR is used by the GDSP to evaluate the effectiveness of the screening program. It is important that the Sickle Cell Disease Center enter information into all the fields of the HSR form, including the Health Profile. An HSR should be completed for significant contacts. This data includes physician telephone consultations, contact with the family in person or by telephone, the initial clinic visit, other physician consultations and follow-up visits for diagnostic evaluation. The final HSR shall document the diagnostic decision and information on the treatment initiated.

The SIS HSR shall be completed as **soon as possible, preferably within one (1) business day but no later than five (5) calendar days** of each significant contact and the diagnostic decision. After a diagnosis is confirmed or ruled out, treatment (if indicated) initiated, and this information entered in an HSR, further HSRs are no longer required for that patient.

SIS Genotype Entry

If genotyping or mutation analysis was done in a laboratory other than the NBS Hemoglobin Reference Laboratory, enter these results in the Confirmatory Test Results section of SIS by selecting “DNA” as the Test Type.

SIS Case Notes

After entering the HSR, Case Notes may be added when additional information is needed to augment or clarify that HSR—for example, when the contact type checked on the HSR is “Other,” for brief explanations, for unusual delays in diagnosis, or for estimate of time until confirmatory results will be available. Other reasons for Case Notes include notes about the date of the next appointment, additional testing ordered, or case status since the last HSR. **However, Case Notes do not replace the need for an HSR when a significant contact is made that provides information about the referred NBS case.**

For a diagnosis taking more than a month, the Center should communicate at least monthly with the ASC regarding the case status. The Center can discuss with the ASC the best way to communicate updates, using one or more modes of contact:
email, telephone, or SIS Case Notes.

SIS Hemoglobin Center Annual Patient Summary

A SIS Hemoglobin Center Annual Patient Summary (HCAPS) must be completed in SIS once a year for each child diagnosed with a hemoglobin disorder for which GDSP screens until the child is five years of age. Each month, Sickle Cell Disease Centers will receive a list in SIS of referred cases of children who had a birthday in the previous month who are due to have an HCAPS. The HCAPS should be completed by the end of the following month (the month after the child’s birthday). Guidelines for completing the HCAPS can be found in the Data Entry Manual. Any questions about SIS and completing the HSRs or the HCAPS should be directed to the Sickle Cell Disease Center Vendor Liaison.

- g. Notify the GDSP by telephone or e-mail each time a new diagnosis of a hemoglobin disorder for which NBSP screens is made at your Center for a patient who **was screened but not identified as *Screen Positive* by the California NBSP, regardless of patient age.**
- h. Notify the GDSP by telephone or e-mail each time a new diagnosis of a hemoglobin disorder for which NBSP screens is made at your Center for a patient up to 5 years of age, who was **not screened by the California NBSP.**

Provide information on name, birthdate, demographic characteristics, and the results of confirmatory testing. Within five (5) days, Center shall complete pertinent information on the HSR screen in SIS on encounters with each new patient who was not initially screened by GDSP, up to the point of diagnosis and initiation of treatment and when the diagnosis is made and treatment initiated for each new patient. Centers also shall complete a SIS HCAPS once a year on each of these new patients until the child is 5 years of age.

- i. The NBSP Sickle Cell Disease Center Vendor Liaison must be notified regarding any changes in the Sickle Cell Disease Center core clinic team members or staff who will be entering information into SIS.

5. Reimbursement

The GDSP shall reimburse the Vendor, using a unit-cost methodology, for each new case referred and for each annual follow-up for diagnosed cases as reported in SIS. See Exhibit B for a detailed outline of the rate schedule. GDSP will provide a report quarterly that contains the number of new referrals and completed Annual Patient Summaries to be used in completing the quarterly invoice for the associated time period.

6. Representation and Participation

The Vendor shall release staff specified by the NBSP to attend regional or statewide meetings planned and convened by the NBSP, i.e., statewide planning meetings, guideline subcommittees, etc. Vendor staff shall assist the GDSP in the further development of the NBSP by recommending and responding to proposed policy changes and providing information as requested.

7. Confidential and Privileged Information

The Vendor shall protect all confidential or privileged information provided by the NBSP. The confidentiality of patient files and records shall be protected by the Vendor in accordance with existing State and Federal laws and regulations.

Confidential or privileged information includes, but is not limited to, any and all information, instructions, calculations, tables, graphs, programming instructions, software, computer discs, and any other materials designated by the NBSP. The Vendor shall ensure that all personnel, including vendors, shall not release any such information to unauthorized persons except as required by law. Such information is not to be used for private gain or profit. The Vendor agrees to notify the NBSP in the event any confidential or privileged information is released without proper authorization. The Vendor agrees to reimburse the NBSP for the costs of enforcing this clause, including any legal fees.

8. Allowable Informal Scope of Work Changes

- a. The Vendor or the State may propose informal changes or revisions to the activities, tasks, deliverables and/or performance time frames specified in the Scope of Work, provided such changes do not alter the overall goals and basic purpose of the agreement. Such informal changes shall not require a formal amendment to the agreement.
- b. Informal SOW changes may include the substitution of specified activities or tasks; the alteration or substitution of agreement deliverables and modifications to anticipated completion/target dates.
- c. The informal change shall not result in an increase or decrease to annual costs under the Agreement.
- d. Unless otherwise stipulated in this agreement, all informal SOW changes and revisions are subject to prior written approval by the State and the Vendor.
- e. In implementing this provision, the State may provide a format for the Vendor's use to request informal SOW changes. If no format is provided by the State, the Vendor may devise its own format for this purpose.

3.4.4. Cystic Fibrosis Center Vendor Agreement and Scope of Work (SOW)

Vendor's Name
11-CFXXX

1. Service Overview

Vendor agrees to provide to the California Department of Public Health (CDPH) the services described herein.

Vendor must be a California Children's Services (CCS) approved Cystic Fibrosis Special Care Center providing multidisciplinary care at the clinic site. CCS approval must be maintained throughout the term of the agreement.

Vendor shall provide a timely diagnosis for cases referred by the CDPH, Genetic Disease Screening Program (GDSP) Newborn Screening Program (NBSP) to prevent morbidity or mortality associated with Cystic Fibrosis as well as to document the referral and diagnostic decision into the GDSP Screening Information System (SIS). **Infants to be referred to the Vendor include those who test positive for Cystic Fibrosis.**

The acceptance of this Agreement certifies that services provided by the Vendor will comply with GDSP program policies, guidelines and protocols for the California Newborn Screening Program. It also certifies that services provided meet national treatment guidelines as appropriate to California.

2. Service Location

The services shall be performed at clinic locations and any CCS-approved satellite clinics.

3. Service Hours

The services shall be provided during normal Vendor working days and hours, and arrangements shall be made for on call coverage during non-business hours.

4. Project Representatives

- a. The project representatives during the term of this Agreement will be

<p>California Department of Public Health Administrator Muslimah Jaavaid Telephone: (510) 412-1476 Fax: (510) 412-1548 Email: MJavaaid@cdph.ca.gov</p>	<p>Vendor's Name Agency Official {Enter name of Vendor's Contract Mgr.) Telephone: (XXX) XXX-XXXX Fax: (XXX) XXX-XXXX Email: XXXXXXXX@xxxx.xxx</p>
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- b. Direct all inquiries to

<p>California Department of Public Health NBSP Cystic Fibrosis Center Liaison Genetic Disease Screening Program Attention: Tracey Bishop Mail Station Code 8200 850 Marina Bay Parkway Richmond, CA 94804 Telephone: (510) 412-6213 Fax: (510) 412-4657 Email: tracey.bishop@cdph.ca.gov</p>	<p>Vendor's Name Project Director Section or Unit Name (if applicable) Attention: (Enter Name) Street Address & room number P.O. Box Number (if applicable) City, State, Zip Code Telephone: (XXX) XXX-XXXX Fax: (XXX) XXX-XXXX Email: XXXXXXXX@XXXX.XXX</p>
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- c. Either party may make changes to the information above by giving written notice to the other party. Said changes shall not require an amendment to this Agreement.

5. Services to be Performed

Vendor shall perform the following services:

- a. Enter into SIS the short-term and long-term reportable data on the referred and diagnosed newborn cases. Reportable data encompasses information related to the consultation with the newborn's Primary Medical Doctor (PMD), Newborn Screening Area Service Centers (ASCs), and the NBSP staff regarding cases referred to the Cystic Fibrosis Center with a positive newborn screening result, as well as providing clinical information to GDSP on conditions screened for by the California NBSP.
- b. Participate in periodic meetings convened and funded by the NBSP to review and consult on the effectiveness of newborn screening, reference ranges, patterns and reporting of results, and follow-up protocols.
- c. Contact the PMD to discuss health status of referred newborns and determine whether it is necessary for the baby to be seen immediately by a specialist. Communicate by telephone, secure fax, or e-mail with PMD, as needed, regarding the status and treatment of the baby.
- d. Respond to ASC or NBSP staff requests for information on referred cases within two (2) business days of request.

- e. Upon request, provide consultation to NBSP staff, ASC staff, newborn's PMD, and/or CCS authorizing agency regarding diagnosis and treatment of Cystic Fibrosis conditions screened for by the GDSP.
- f. SIS Documentation

Using the GDSP Web-based SIS, provide timely documentation of significant contacts pertaining to a referred infant. New cases will appear in the top grid of the SIS Follow-Up Center Cases Referred screen. After follow-up consultation activities have been initiated and documented on a SIS Cystic Fibrosis Service Report indicating that the case has been received at the Cystic Fibrosis Center, the case will move to the "PENDING" grid. Once a diagnosis is confirmed or ruled out, the case will move to the third grid, "RESOLVED CASES."

Sweat Chloride Result

Enter sweat chloride test result into confirmatory test result section of SIS when received (within 2 business days of receipt).

SIS Cystic Fibrosis Service Report

The online SIS Cystic Fibrosis Services Report form (CFSR) is a mechanism for documenting significant contacts made regarding a referred infant from the time of initial referral until the diagnostic decision is made and any necessary treatment is initiated. The information gained from the CFSR is used by the GDSP to evaluate the effectiveness of the screening program. It is important that the Cystic Fibrosis Center enter information into all the fields of the CFSR form, including the Health Profile. A CFSR should be completed for significant contacts. This data includes physician telephone consultations, contact with the family in person or by telephone, the initial clinic visit, other physician consultations, and follow-up visits for diagnostic evaluation. The final CFSR shall document the diagnostic decision and information on the treatment initiated.

The SIS CFSR shall be completed as **soon as possible, preferably within one (1) business day but no later than five (5) calendar days** of each significant contact and the diagnostic decision. After a diagnosis is confirmed or ruled out, treatment (if indicated) initiated, and this information entered in a CFSR, further CFSRs are no longer required for that patient.

SIS Case Notes

After entering the CFSR, Case Notes may be added when additional information is needed to augment or clarify that CFSR—for example, when the contact type checked on the CFSR is "Other," for brief explanations, for

unusual delays in diagnosis, or for estimate of time until confirmatory results will be available. Other reasons for Case Notes include notes about the date of the next appointment, additional testing ordered, or case status since the last CFSR. However, **Case Notes do not replace the need for a CFSR when a significant contact is made that provides information about the referred NBS case.**

For a diagnosis taking over a month, the Center should communicate at least monthly with the ASC regarding the case status. The Center can discuss with the ASC the best way to communicate updates, using one or more modes of contact: e-mail, telephone, or SIS Case Notes.

SIS Cystic Fibrosis Center Annual Patient Summary

A SIS Cystic Fibrosis Center Annual Patient Summary (CFAPS) must be completed in SIS once a year for each child diagnosed with Cystic Fibrosis or CFTR Related Metabolic Syndrome (CRMS) until the child is five years of age. Each month, Cystic Fibrosis Centers will receive a list in SIS of referred cases of children who had a birthday in the previous month who are due to have a CFAPS. The CFAPS should be completed by the end of the following month (the month after the child's birthday). Guidelines for completing the CFAPS can be found in the Data Entry Manual. Any questions about SIS and completing the CFSRs or the CFAPS should be directed to the Cystic Fibrosis Center Vendor Liaison.

Some Cystic Fibrosis cases taking more than 9 months to resolve at the Cystic Fibrosis Center will be followed directly by staff at the GDSP. Cystic Fibrosis Centers will be contacted directly by GDSP staff concerning extended case follow-up and given instructions about any additional information that is needed. CFSRs still need to be kept current on these cases until they are resolved.

- g. Notify the GDSP by telephone or e-mail each time a new diagnosis of Cystic Fibrosis is made at your Center for a patient who was **screened but not identified as *Screen Positive* by the California NBSP, regardless of patient age.**
- h. Notify the GDSP by telephone or e-mail each time a new diagnosis of Cystic Fibrosis is made at your Center for a patient up to 5 years of age, who **was not screened by the California NBSP.** Provide information on name, birthdate, demographic characteristics, and the results of confirmatory testing. Within five (5) days, Center shall complete pertinent information on the CFSR screen in SIS on encounters with each new patient who was not initially screened by GDSP, up to the point of diagnosis and initiation of treatment. Centers also shall complete a

SIS CFAPS once a year on each of these new patients until the child is 5 years of age.

- i. The NBSP Cystic Fibrosis Center Vendor Liaison must be notified regarding any changes in the Cystic Fibrosis Center core clinic team members or staff who will be entering information into SIS.
- j. Fax copies of laboratory reports with the results of CF DNA mutation analysis of the newborn's parents to the GDSP for entry into SIS to Marty Kharrazi, Fax number (510) 412-1511.
- k. Accept referrals from NBSP CF Carrier Follow-up program for parents of newborns with a single CF gene mutation identified via the NBSP who have already received phone counseling from NBSP's Genetic Counselor or who have requested face-to-face counseling in lieu of telephone counseling.

6. Reimbursement

The GDSP shall reimburse the Vendor, using a unit-cost methodology, for each new case referred and for each annual follow-up for diagnosed cases as reported in SIS. See Exhibit B for a detailed outline of the rate payable schedule. GDSP will provide a report quarterly that contains the number of new referrals and completed Annual Patient Summaries to be used in completing the invoice for the associated time period.

7. Representation and Participation

The Vendor shall release staff specified by the NBSP to attend regional or statewide meetings planned and convened by the NBSP, i.e., statewide planning meetings, guideline subcommittees, etc. Vendor staff shall assist the GDSP in the further development of the NBSP by recommending and responding to proposed policy changes and providing information as requested.

8. Confidential and Privileged Information

The Vendor shall protect all confidential or privileged information provided by the NBSP. The confidentiality of patient files and records shall be protected by the Vendor in accordance with existing State and Federal laws and regulations.

Confidential or privileged information includes, but is not limited to, any and all information, instructions, calculations, tables, graphs, programming instructions, software, computer discs, and any other materials designated by the NBSB. The Vendor shall ensure that all personnel, including vendors, shall not release any

such information to unauthorized persons except as required by law. Such information is not to be used for private gain or profit. The Vendor agrees to notify the NBSP in the event any confidential or privileged information is released without proper authorization. The Vendor agrees to reimburse the NBSP for the costs of enforcing this clause, including any legal fees.