Committee for the Protection of Human Subjects cphs

PROTOCOL
Request for CPHS Approval
Committee for the Protection of Human Subjects

Protocol Title: Longitudinal Study of Hospital Outcomes for California's Children
Protocol Type: Request for CPHS Approval
Date Submitted: 03/02/2016
Approval Period: 04/01/2016-03/31/2017
Important Note: **This Print View may not reflect all comments and contingencies for approval. Please check the comments section of the online protocol. Questions that appear to not have been answered may not have been required for this submission. Please see the system application for more details.**

1

*** * * Continuing review * * ***

Continuing Renewal:

1. Has the analysis of data and/or involvement of human subjects permanently ended? This includes contact, enrollment, and interventions? (If Yes, describe below) N
2. Have any complaints (verbal or written) been received from data sources/study participants? (If Yes, describe below) N
3. Have there been any adverse events? (If Yes, describe below) N
4. Have there been any breaches of data security? (If Yes, describe below) N
5. Have there been any difficulties or unanticipated problems experienced during the research? (If Yes, describe below) N
6. Are you requesting any changes to your approved protocol, including use of additional years of data? (If "Yes", please specify and justify revisions and address whether revisions change subjects' risk level in the box below.) N
7. Date subject enrollment/data collection began: 01/01/1983
8. Number of proposed subjects/data records: millions added annually

Protocol Title: Longitudinal Study of Hospital Outcomes for California's Children

a. Total number of subjects enrolled/data records analyzed since project began (active and inactive): Millions
b. Number of subjects/data records currently active in project: Millions
c. Number of subjects offered enrollment in past year (not applicable for data-only): NA
d. Number of subjects who declined enrollment in the past year (not applicable for data-only): NA
e. Total number of subjects withdrawn since project began (Human subject contact). Number of data records deleted in the past year (Data-only) (attach reasons): None
f. Number of subjects expected to enroll/data records expected to be analyzed in coming year: millions
g. Expected total number of subjects/data records in project: millions

9. Expected completion date of project: longitudinal, ongoing

10. HIPAA - has there been any changes in data security practices or other factors that may be relevant to the waiver for HIPAA waiver of authorization, if applicable? N

11. Project Chronology - provide a dated sequence of significant events in the project's history, including all changes reviewed by CPHS in the box below. Originally approved in 1996. Major changes since then have been to add years of data.
12. Interim Findings - provide a summary statement of interim findings and other relevant information in the box below: We have been working on putting all our SAS-related resources on our website.

Attach any reports, literature, or publications related to this research in the Attachments Section.

*** * * Personnel Information * * ***

Principal Investigator (required)

Name	Title	Credentials
Geraldine Oliva	Adjunct Assoc. Professor	M.D., MPH

Protocol Title: Longitudinal Study of Hospital Outcomes for California's Children

Email : olivag@fcm.ucsf.edu
Phone
Fax

Organization Name: University of California, San Francisco
Additional Organizational Information: Family Health Outcomes Project
Mailing Address:
500 Parnassus Ave. Room MU-337
San Francisco CA 94143-0900
Alternate Phone

Training data is not currently needed

Co-Principal Investigator (if applicable)
Name: Linda Remy Title: Research Director/Sr. Statistician Credentials: MSW PhD
Email: lremy@well.com
Organization Name: University of California, San Francisco
Additional Organizational Information: Family Health Outcomes Project
Mailing Address: 14 Cliff Road Belvedere CA 94920

Alternate Phone

Training data is not currently needed

Responsible Official (required)
Name: Kevin Grumbach Title: Professor Credentials: MD

Email: kgrumbach@fcm.ucsf.edu

Organization Name
Additional Organizational Information: Chair, Family and Community Medicine
Mailing Address:
1001 Potrero Ave, SFGH 80 WD
83
Box SFGH - B80 WD83
University of California, San Francisco
San Francisco, CA. 94143
Alternate Phone

PROTOCOL
Request for CPHS Approval
Committee for the Protection of Human Subjects

Protocol Title: Longitudinal Study of Hospital Outcomes for California's Children

---

4

Training data is not currently needed

Additional Contact (optional)
Name: Rienks, Jennifer
Title: Associate Director, Family Health Outcomes Project
Credentials: PhD

Email: jennifer.rienks@ucsf.edu
Phone
Fax
Organization Name: University of California, San Francisco
Additional Organizational Information
Mailing Address
Alternate Phone

Training data is not currently needed

*** * * Vulnerable Population Checklist * * ***

Vulnerable Population(s) Checklist

Select All That Apply :

Minors (In the United States, a minor is under 18 years of age. If research is conducted outside the United States, a minor is under the age of majority in the countries where research is to be conducted.)

Prisoners

Pregnant Women, Fetuses, and/or Neonates

X Not Applicable

Other

*** * * Study Location * * ***

Study Location(s)

X Not applicable

Study Location (specify below)

*** * * General Checklist * * ***

Project Type

Death-Data Only

X SB-13 (Information Practices Act)

Common Rule

Protocol Title: Longitudinal Study of Hospital Outcomes for California's Children

5

Includes:

X Minimal Risk
Non-English Translation
X HIPAA Waiver Consent Form Assent Form
Reliance Agreement Relying on CPHS Reliance Agreement with Another IRB

*** * * Funding * * ***

Funding Source(s) None
Funding

Funding Administered By	Funded By	Amount of Funding
State	California MCAH	250,000

*** * * Expedited Paragraphs * * ***

Please check the criteria below that you think your project meets to qualify for an expedited review. If none of these expedited criteria are appropriate for your project, please move to the next screen without selecting any of these criteria; your protocol will be reviewed by the full committee.

New project requesting only previously existing *personally identifiable data or specimens (PIDS) from departments outside of **the California Health and Human Services Area (CHHSA). (Information Practices Act (IPA) review)

New project requesting only previously existing PIDS and not involving state research staff, funding or state mental hospital patients from departments within the CHHSA (IPA review)

X New project requesting only previously existing PIDS involving CHHSA department funding , research staff or patients from state mental hospitals (Common Rule review)

Death data-only projects (Death Data review)

Note that CPHS will make the final determination of whether the project meets the criteria for expedited review.

* PIDS is defined as existing data or specimens including any of the 18 HIPAA identifiers. http://www.oshpd.ca.gov/Boards/CPHS/HIPAAIdentifiers.pdf

**The Departments within the CHHSA are: Aging, Alcohol and Drug Programs, Child Support Services, Community Services and Development, Developmental Services, Emergency Medical Services Authority, Health Care Services, Mental Health, Public Health, Rehabilitation, Social Services, Statewide Health Planning and Development

*** * * Purpose, Study Procedures, Testing of a New Drug or Devices * * ***

Original Project Number (#00-00-00):
96-06-02

Title (Please indicate if the protocol title is different from the proposal title)
Longitudinal Study of Hospital Outcomes for California's Children

Start Date: 06/12/1996

End Date: 06/30/2022

Complete Sections 1 - 11. Specify N/A as appropriate. Do not leave any sections blank.

1. Purpose of the study

a. Include a brief statement , less than 500 words, describing the research project. Be sure to address the background for the project, including relevant literature, the major research questions to be addressed, and the expected end product (e.g., article, report or other publications). Include the location(s) where the project will take place. The summary should be understandable to the general public.

In 2015, we are amending this protocol to explicitly add the life course perspective, which has been a driving force behind our work. After many years of discussion, California MCAH formally adopted it. We wish to make the model explicit at this time because MCAH finally incorporated it, and as the years of data accumulate, it becomes increasingly possible to design studies applying it.
Suppose a pregnant woman age 24 is admitted to hospital for substance abuse in 1991. In applying the life course model, one would follow this woman over time by linking records, to study the impact of early substance abuse on later health outcomes. We presently can follow her from 1991 through 2012, or 21 years, or in the present instance until she is about 45, the upper age of the reproductive period. With the life course model, we continue to monitor her health outcomes as she ages and as we accumulate more years of data.
We used this model to inform several earlier studies, one on mental health, another on pregnancy outcomes, and a recent paper focusing on long-term health outcomes in the community of Willits, which was exposed to toxic chemicals for decades. The best-known studies using this approach examine the long-term impact of the World War II famine in Holland, now following through to the third generation. Although a number of longitudinal studies employ sampling designs, longitudinal population-based studies

focused on the life course are very rare in the United States, because we were so late to develop linkable data sets relative to the European nations. OSHPD data, in particular, finally has accumulated to a point where such studies are increasingly possible. This is why we began so long ago to accumulate these important population data sets and why we have spent so many years developing tools to analyze longitudinal data. Making the life course model explicit has no impact on the types of conditions or populations we study, it just reflects the steadily increasing length of time we are able to follow our populations. Methodologically, we develop software to unduplicated and link records longitudinally within and across various confidential administrative data sets. Related to this is the software we developed to classify cases into mutually exclusive conditions based on combinations of diagnoses and/or procedures. Another area of software development involves tools to summarize data to various geographic levels, either before or after modeling depending on the research needs, and then store results. The last component of software development focuses on tools to automate preparation of tables, figures, spreadsheets, and maps.

Analytically, depending on the task at hand, we use confidential individual-level files to create various combinations of unduplicated, linked, longitudinal, multi-level files to understand changes in patterns of health care over time, access to and quality of care, and outcomes. Analytic studies typically involve other non-confidential data sets to create contextual variables. These latter data sources include census, population, and/or other files. Results of scientific analyses are incorporated into reports and other products provided to our funders, including the California Department of Public Health (DPH), local DPH, the public, and the scientific community. Our applied research work has two related strands. First, using confidential data sets as the base source, we prepare longitudinal non-confidential data sets, maps, spreadsheets, and other products at administrative levels (census tract or block, ZIP, county) for distribution to local DPH through protected sections of our website and to the public through our website or the DPH website. Second, we develop software and training materials to help local DPH use these data for their mandated planning and surveillance activities. In addition, we develop various Excel-based templates and macros to calculate relevant statistics and produce trend charts to support local monitoring and planning activities.

f

b. What is the major research question to be addressed in this project?

Research questions depend on the nature of the task we are doing. Analytic studies generally focus on longitudinal changes in access and outcomes for various populations, to understand if public health indicators are improving or worsening. The methodologic and applied research does not have research questions per se.

2. Study Procedures

a. Describe all study procedures. Please note: The box below is for text only. If you would like to add tables, charts, etc., attach those files in the Attachment section.

Our primary study procedures involve writing SAS macros and related infrastructure to automate and standardize as much as possible the creation of longitudinal files for various purposes. We demonstrate the use of these programs by designing longitudinal studies that incorporate these resources. We distribute to the public health community these software tools, related methods report, various applied products developed using them, and results of research conducted using them .

b. State if audio or video taping will occur. Describe how the tapes will be maintained during and upon completion of the project. Describe what will become of the tapes after use (e.g., shown at scientific meetings, erased, etc.).

c. State if deception will be used. If so, provide a rationale and describe debriefing procedures. Submit a debriefing script in the Attachment section.

Protocol Title: Longitudinal Study of Hospital Outcomes for California's Children

3. Testing of a New Drug or Devices

a. Is a new drug or device being tested or used in the research project? If yes, attach copies of any state and/or federal documents that permit the investigator(s) to proceed with research.
b. Describe the procedures, such as use of a data monitoring committee, to be used for adequately monitoring the safety of the subjects involved in testing a new drug or device.

4. Study Affiliation

a) If data or specimens from departments within the State of California are being requested, list the department name and the formal name of the data base or specimen registry.
CDPH 1989 -2013 confidential birth and death files and 1989-2013 confidential fetal death files are in our possession. We previously were approved to receive these data from 1983 through 2018, as they become available.
OSHPD 1983-2014 confidential patient discharge and 2005-2014 confidential emergency department and ambulatory data are in our possession. We previously were approved to receive these data through 2018 as they become available.

b) List any California Health and Human Services Agency department(s)' involvement in providing research staff, funding and/or patients from State mental hospitals for this project.
We currently receive funding from CDPH Maternal Child and Adolescent Health. Over the many years this protocol has been in existence, we have had various other funding sources such as other California State agencies, foundation and federal grants. Our protocol has been independent of our funding sources.

5. Subject Population

In the space below, please describe the participants that you are requesting to recruit (include requested participant number and description of each group requested).For data-only studies ,describe the databases or records to be accessed and the data elements to be obtained.

a) Provide a full description of how human subjects will be involved in the research. Address characteristics of subjects, such as age, sex and ethnicity and number of participants.

Protocol Title: Longitudinal Study of Hospital Outcomes for California's Children

b) If existing data will be obtained, list the database(s) to be used, the time period(s) being requested. This may include requests for future data that is not available at this time. List or attach a list of variables (in the Attachment Section, Attachments) being requested and justify the need for each variable and for the quantity of data being requested. Also, will participants be involved in any other studies?

At this time we are requesting to receive 2014-2018 confidential files as they become available from the following sources: CDPH birth, death, fetal death master statistical files, and OSHPD discharge, emergency, and ambulatory data.

See attachments for variables needed and justification for OSHPD variables that they requested of us. HISP has not requested a similar justification for the birth, death, or fetal death files. However, we have included lists of the variables we have been using for many years, from the 2009 file. Note that earlier years had other variables that were discontinued or replaced.

We need all variables in the files, as they become available. We cannot begin a longitudinal study only to find that we do not have a variable that was available 20 years earlier.

c) What is the rationale for studying the requested group(s) of participants?

d) Describe how potential subjects will be identified for recruitment. Examples include: class rosters, group membership, individuals answering an advertisement, organization position titles (i.e., Presidents, web designers, etc.). How will potential participants learn about the research and how will they be recruited (e.g., flyer, email, web posting, telephone, etc.)? Attach recruitment materials in the Attachment Section, Attachments. Important to remember: subjects cannot be contacted before IRB approval.

Will you be using recruitment materials ?

e) Screening Procedures: If subjects will be screened prior to entry into the research, please address the criteria for exclusion and inclusion in the research. Provide reasons for not including women or minorities. Provide justification for including vulnerable populations such as children or prisoners. Please also provide a statement regarding what will happen to the information collected about the individual should they not enter into the study.

f) Explain the amount, nature, e.g.; gift card, cash, and schedule of compensation, if any, that will be paid for participation in the study. Include provisions for prorating payment. The amount should not be coercive.

g) Estimate the probable duration of the entire study. This estimate should include the total time each subject is to be involved and the duration the data about the subject is to be collected (e.g., This is a 2-year study. Participants will be interviewed 3 times per year; each interview will last approximately 2 hours. Total approximate time commitment for participants is 12 hours.)

A longitudinal population health study by definition, this work will be ongoing for many years.

. Risks, Benefits

6. Risks (Input N/A if not applicable)

Protocol Title: Longitudinal Study of Hospital Outcomes for California's Children

---

US Department of Health & Human Services (HHS) Regulations define a subject at risk as follows: "...any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service."

a) **Provide description of risk, physical, psychological, social or economic, loss of data security and confidentiality to subjects. Describe and justify risk level (minimal, moderate or high).**
Previous human subjects reviews have ruled that our research involves minimal risk to subjects. Our use of the data does not adversely affect the rights and welfare of the subjects. Due to the longitudinal nature of our research, we have no way to know current whereabouts, and many are deceased . We have rigorous procedures in place to protect the data. Finally, the research could not practicably be conducted without access to confidential variables. We never release identifiable individual-level data to anyone for any reason. We minimize the possibility of the loss of data security by using encrypted drives with different passwords at different levels: bios, entry to the operating system (Windows 7), and yet a third on external backup drives with unencrypted original data. The original data are stored in ZIP files protected with yet another password . We restrict confidential data access to two people: Dr. Remy, the Co-Principal Investigator who wrote the protocol, and Ted Clay, who has been working with Dr. Remy since the late 1980s before either came to UCSF. Dr. Remy came to UCSF in 1989, and asked Mr. Clay to join her in the early 1990s. Both have been with FHOP since 1996. The risk level is minimal.

b) **If death data is being used, include risk to estate of deceased or living person by use of the death data.**
There is no risk to estate of deceased or living person with our use of the death data. We encrypt name and addresses when available, and store those separately. We only use names or addresses when we are linking data, doing small area geocoded studies, or when we are studying data quality. We never release identifiable individual-level data to anyone.

c) **If audio/video taping will be used, state if it could increase potential risk to subject's confidentiality.**
d) **Describe how medical services will be provided if subjects suffer adverse mental or physical effects as result of research activity. If no services provided state clearly.**
e) **In the case of overseas research, describe qualifications/preparations that enable you to evaluate cultural appropriateness and estimate/minimize risks to subjects.**
f) **Describe any less risky methods and why they are not being used.**

7. Benefits

a) **Benefits: Describe the benefits, if any, to the subjects or to society that will be realized as a result of this project. Discuss the benefits that may accrue directly to the subjects as well as to society. If there is no direct benefit anticipated for the subjects, please state such.**
Policy makers, consumer advocates, insurance carriers, and employers may benefit since the focus is to monitor changes in access to healthcare and to identify possible explanations for those changes for California's reproductive age population, and for children, adolescents, and young adults. Policy makers at

Protocol Title: Longitudinal Study of Hospital Outcomes for California's Children

the local, state and national level receive detailed information to help them understand the consequences of rapid changes in health care policy. Consumer advocates may use the information to help organize community groups and to lobby legislators. Results may be useful to insurance carriers and employers deciding what diagnoses to monitor in evaluating health insurance plan performance. This project benefits the research community in that it extends linkage methods developed by earlier UCSF researchers. Finally, the most benefit, in the long run, may accrue to California's youngest and most vulnerable citizens and their concerned parents.

b) Explain why study risks are reasonable in relation to the potential benefits to subjects and to society.

*** * * Data Security Requirements Administrative Safeguards,Physical Safeguards,Electronic Safeguards * ***

8. Administrative Safeguards

a) Describe the procedures for training all research staff, who have access to PID on privacy and security. Indicate if staff are required to sign a confidentiality statement related to general use, security and privacy.

UCSF requires all research staff to complete training on PID at regular intervals. Researchers who have not completed their training timely are not allowed to continue to work until they do so.

b) Describe procedures, either background check or thorough reference check, for vetting staff, who will have access to PID.

UCSF requires rigorous background checks on everyone when they begin to work at our institution. We have never had to do a background or reference check on anyone associated with this protocol because they already were at FHOP before it first was approved. Access to confidential data is restricted to two people: Dr. Linda Remy, the project's Co-Principal Investigator, and Ted Clay, who has worked with Dr. Remy since the 1980s.

c) Indicate whether you have obtained and submitted to CPHS a statement from the state agency or department you are receiving data from. That statement should include that the release of the desired data is legal, and that the entity is willing to release the desired data to you, the researcher.

We separately submit data requests to OSHPD and to Vital Statistics for their respective data sets. We understand that their authorization to release more years of data relies on renewal of this protocol for another year.

d) Explain how you will ensure that data will not be reused or provided to any unauthorized person or entity (unauthorized means that the person or entity does not have a need to access the data for purposes of the research project approved by CPHS?

Confidential data is accessible only by two people who know multiple passwords that are very carefully protected. The data are stored on encrypted drives and original data is further protected in password-protected ZIP files.

e) Indicate whether information will not be published that could possibly be used to identify an individual subject.

We never release any information that could possibly identify an individual. Several times in the past, we came voluntarily to ask for review of the display of summary data for our various data products. The conclusion always has been that the way we were grouping data did not identify any individual person.

f) **Provide adequate justifications for the quantity of the data, the years and the variables being requested. Have you requested no more than the minimum necessary data to perform the research?** Twenty years ago, we began an ambitious longitudinal research agenda focusing on the health of California's families. Working under the existing protocol, we have conducted many different analyses over that interval, each using different combinations of variables and data sets. We cannot begin a longitudinal study and discover that we did not obtain a certain variable from a file made twenty or thirty years ago. To

protect against that possibility, the original reviewers approved us having all variables in all data sets we request and approved our access to new variables as they became available. A major aspect of our longitudinal research task has been to understand the changes in available variables so we can adapt our methods to adequately report on and model the changing health landscape.

g) Indicate if access to data limited only to those with a need to know for purposes of implementing or evaluating the research.

Only two people have access to these data. They have been the same two people since the study first was approved in 1996: Dr. Linda Remy, the study's Co-Principal Investigator, and Ted Clay, who writes our macros.

h) If applicable, justify why unique identifiers, other than social security numbers, cannot be used.

Dr. Remy and Mr. Clay developed the Encrypted Social Security Number (ESSN) in the early 1990s while both worked with Harold Luft at the UCSF Institute for Health Policy Studies, to link records for California's first hospital outcome studies. OSHPD's encryption algorithm transposes the order of digits within the social security number (SSN). A one-digit data entry error results in an RLN that cannot be soft-matched correctly. Further, the RLN is not available on other data sets with which we routinely link. We use the ESSN to link to records in death certificates. Vital Statistics no longer permits us to use the ESSN in birth certificates. Note that SSN, names and addresses are encrypted using the same algorithm. We use the ESSN as part of the soft-matching algorithm to strengthen the linkage, especially for analyses focusing on episodes of care.

Linkage is vital to identify people transferred from facility to facility for one episode of care, or multiply admitted for the same condition. We require detailed date information (birth, admission, procedure, discharge, injury, death, etc.) to create condition-relevant age cutoffs and to monitor care for the same person over time. Admission and discharge dates are used to identify episodes of care, a major problem which must be overcome to develop accurate condition rates. Our goal in linked research studies is to create rate measures based on unduplicated counts of "people", after accounting for transfers and readmissions for the same condition.

Five-digit ZIP codes are used as part of the linkage algorithm to identify episodes of care. They also are used to perform small area analyses and compare patterns of hospital use across micro-geographical areas. The capacity to do such analyses at a county level greatly enhances planning and assessment for local public health directors.

We use names to continue to test and refine our methods to create unique identifiers, and we need specific addresses to do better small area mapping. HISP has asked us to do various studies evaluating data quality and geocoding using address variables. Specific addresses are immune to the problems of changing administrative boundaries from census to census or by changing mail delivery patterns of the United States Postal Service.

i) Described appropriate and sufficient methods to protect the identity of individual subjects when small cells or small numbers and/or data linkage to another data set are involved in the research project.

We never report fewer than 10 cases in a year. If we have fewer than 10 cases, we summarize to a 2-year period, and then to a 3-year period if needed. OSHPD previously ruled that the results of our algorithm did not identify individual people in small number situations when data were presented in 3-year intervals. In data tables, we do not report fewer than 5 cases. We are waiting for revised small number policies from the California Department of Public Health before we update our small numbers monograph.

j) **If the data set is to be linked with any other data sets, identify all data sets and each of the variables to be linked, with justification for each linkage. If there is an extensive list, include the list as an attachment, in the Attachment Section**. Variables that we use depend on the nature of the study and what is available in each of the datasets to be linked. If data are individual-level, and the SSN is available in both sets, we typically use sex, birth date (or age), race/ethnicity as confirmatory variables, and sometimes add geography variables. For example, if someone was injured and died, we would compare the ZIP-code of the hospital record with the ZIP-code of place of death in the death file.

Protocol Title: Longitudinal Study of Hospital Outcomes for California's Children

We have done numerous studies merging OSHPD data with death data. In exploratory studies to evaluate data quality, we have merged OSHPD and birth data, and birth and death data. We have done a great deal of work addressing ways to merge datasets without SSN, including research to make a universal identifier that was not based on SSN. When we make Vital Statistics files, we encrypt all names, addresses and set them aside. If it is available, the encrypted SSN remains in the main file. When data are summarized into groups, as for the DataBooks, we typically are linking based on year, place of residence (various geography levels), and other variables depending on the groups to be studied.

k) **If a third party is being used to perform data matching, provided evidence of the third parties' ability to protect PID, including third parties' ability to comply with all the CPHS data security standards**

No third party performs data matching. Dr. Remy is the only person who matches or links records, using macros written by Mr. Clay.

l) **Indicate that you will provide CPHS with a letter certifying that PID has been destroyed and/or returned to the data source once research is concluded.**
Once research is concluded, we will provide CPHS with a letter certifying that data sets with PID have been destroyed and/or returned to the data source .

m) **Include a certification from the Chief Information Officer, Privacy Officer, Security Officer or equivalent position of the researcher's institution that CPHS Data Security Standards are met.A letter or statement assuring these standards are met from this individual on organizational letterhead may be included as an attachments in the Attachment Section.**
See data security requirements letter from Dr. Remy.

9. Physical Safeguards

a) **Indicate that research records and physical samples will be protected through the use of locked cabinets and locked rooms; PID in paper form will not be left unattended unless locked in a file cabinet, file room , desk, or office.**

Research records are protected through the use of locked cabinets and rooms. PID in paper form are not left unattended. Basically, we do not have PID in paper form.

b) **State whether data/samples will be destroyed or returned as soon as it is no longer needed for the research project.**

The data will be destroyed or returned as soon as it is no longer needed for the research project.

c) **If samples are to be retained, will they have personal identifies or be de-identified?**
N/A

d) **Describe how you will ensure the PID in paper form is disposed of through confidential means, such as crosscut shredding or pulverizing.**
Should we have PID in paper form, we shred or otherwise pulverize.

e) **Describe how you will ensure that faxes with PID are not left unattended and fax machines are in secure areas.** As a policy, we do not send faxes with PID shown. The two people who access confidential data are the only people who work in their offices

f) **Indicate whether mailings of PID are sealed and secured from inappropriate viewing; mailings of 500 or**

Protocol Title: Longitudinal Study of Hospital Outcomes for California's Children

more individually identifiable records of PID in a single package, and all mailings of PID to vendors/contractors/co-researchers are sent using a tracked mailing method, which includes verification of delivery and receipt, such as UPS, U.S. Express Mail, or Federal Express, or by bonded courier.
When we must send confidential files to Mr. Clay, they are on DVDs, in zipped and password-protected files. We send them by UPS, Federal Express or Express mail, with verification of delivery and receipt. Passwords are transmitted separately from the data.

g) State whether PID in paper or electronic form, e.g., stored on laptop computers and portable electronic storage media (e.g., USB drives and CDs), will never be left unattended in cars or other unsecured locations. . By policy, we do not allow data with PID to be stored on laptop computers. We back up confidential and other data on portable electronic storage media which are both encrypted, and password protected. These drives are stored in secure locations when not in use. They are never left unattended in cars or other unsecured locations.

h) Describe whether facilities, which store PID in paper or electronic form, have controlled access procedures, and 24-hour guard or monitored alarm service. Only people invited by Dr. Remy or Mr. Clay can enter their offices.

i) Provide a description of whether all servers containing unencrypted PID are housed in a secure room with controlled access procedures. We do not use servers. Dr. Remy and Mr. Clay use workstations.

j) Indicate whether identifiers will be stored separately from analysis data. Encrypted names and addresses are stored separately from other data. When available, the ESSN is used as a linkage variable. However, because it is encrypted, it is not identifiable to a specific person.

k) State whether all disks with PID will be destroyed. All disks with PID will be destroyed when the data are no longer needed.

10. Electronic Safeguards

a) **State whether all computer access be protected through the use of encryption, passwords, and other protections.** All computers are protected in multiple ways through the use of encryption, passwords, and other methods.

b) **Indicate whether all workstations that contain PID have full disc encryption that uses FIPS 140-2 compliant software**. All research data are on workstations with full disk encryption using FIPS 140-2 compliant software.

c) **Indicate if all laptops that contain PID have full disc encryption that uses FIPS 140-2 compliant software** We do not allow PID to be on laptops. However, it happens that both Dr. Remy and Mr. Clay use FIPS 140-2 compliant software to protect their laptops.

d) **Note if PID on removable media devices (e.g. USB thumb drives, CD/DVD, smartphones, backup tapes) are encrypted with software which is FIPS 140-2 compliant.** PID on removable media devices are encrypted with software which is FIPS 140-2 compliant.

e) **Indicate if all workstations, laptops and other systems that process and/or store PID have security patches applied in a reasonable time frame.** The computers on which Dr. Remy and Mr. Clay work check for security patch updates, and all patches

Protocol Title: Longitudinal Study of Hospital Outcomes for California's Children

are applied as they become available.

f) **Indicate if sufficiently strong password controls are in place to protect PID stored on workstations, laptops, servers, and removable media.** Dr. Remy and Mr. Clay have checked the strength of the various passwords they use, and all are very strong.

g) **Indicate if sufficient system security controls are in place for automatic screen timeout, automated audit trails, intrusion detection, anti-virus, and periodic system security/log reviews?** Sufficient system security controls are in place for automatic screen timeout, automated audit trails, intrusion detection, anti-virus, and periodic system security/log reviews.

h) **Explain whether all transmissions of electronic PID outside the secure internal network (e.g., emails, website access, and file transfer) are encrypted using software which is compliant with FIPS 140-2.** We never transmit electronic PID via email, website, or electronic file transfer. However, if we did, the files would be encrypted using software which is FIPS 140-2 compliant.

i) Note if PID in an electronic form will be accessible to the internet. No PID in an electronic form will be accessible to the internet.

j) **When disposing of electronic PID, indicate whether sufficiently secure wiping, degaussing, or physical destruction will be used** When drives with electronic PID are phased out, UCSF has a system in place to securely wipe, degauss, and physically destroy the media.

*** * * Conflict of Interest * * ***

11. Conflict of Interest

Describe any financial or other relationships of the researcher(s) or the institution that could be perceived as affecting the objective conduct of the research, including the interpretation and publication of the findings. Financial relationships to be disclosed include but are not limited to the following:

Present or anticipated ownership of stock, stock options, or other financial obligations of the source of funding.

Receipt or expectation of payment of any sort in connections with papers, symposia, consulting, editing, etc. from the source of funding.

The sale or licensing or anticipated sale or licensing of medical or other products or intellectual property, such as patents, copyrights, or trade secrets to the source of funding or other entities.

Any past, present or anticipated receipt of money or other valuable consideration from the source of research funding by the researcher(s), the family of the researcher(s), the research institution, or by an

institution in which the researcher(s) or the family of the researcher(s) has an interest as owner, creditor, or officer.

Does any member of the study team, members' spouses, or members' dependent children have any significant financial interests related to the work to be conducted as part of the

Protocol Title: Longitudinal Study of Hospital Outcomes for California's Children

above-referenced project? N

Name of Personnel with Financial Conflict of Interest

Other research staff that may have a conflict. Please specify below.
Any member of the study team who answers in the affirmative must be listed in the box below.

A staff person will contact any researcher listed above to obtain additional information regarding the specific financial interest(s).

I certify that all members of the study team have answered the financial interests question Y and only those individuals listed in the box above have disclosed any financial interest related to this study.

*** * * Informed Consent * * ***

12. Informed Consent

Provide a description of procedures to be used in obtaining and documenting the prior informed consent of participants. Further CPHS instructions and consent format may be found on the CPHS website link: http://oshpd.ca.gov/Boards/CPHS/index.html

Non-English versions of consent/assent forms or scripts must be submitted as attachments in the Attachment section , along with the curriculum vitae of the translators(s) and/or proof of certification of the translation firm. CPHS may reject poorly written documents or documents from translators lacking adequate proof of training or expertise. In general, Spanish translation should use formal language.
CPHS may approve the use of a consent procedure which does not include, or which alters, some or all of the elements of informed consent. If a waiver or alteration of informed consent is being requested, provide information as to how all of the criteria below will be satisfied.

Attachments Section

*** * * Assent Background * * ***

13. Assent Background

Protocol Title: Longitudinal Study of Hospital Outcomes for California's Children

Provide a description of procedures to be used in obtaining and documenting the prior assent of participants. Further CPHS instructions and assent format may be found on the CPHS website link: http://oshpd.ca.gov/Boards/CPHS/index.html

While the intent of informed assent is the same as that of informed consent, the informed assent must be written at a level that is understandable to potential participants who are children between the age of 7-17 years of age. Different informed assent forms may be needed if the study involves children of significantly different ages. The same headings must be used. Because some children cannot read through as long a form as an adult, assent forms may be shortened to facilitate reading and understanding by children.
However, all of the required elements of the informed consent must still be adequately addressed. The CPHS website link to the format and additional instructions is : http://www.oshpd.ca.gov/Boards/CPHS/InstructionsforResearchers.pdf#Untitled (53).

See sample assent/consent forms at http://www.keyusa.com/human-subjects.html
If applicable, provide assent process background information for each Assent Form, Alteration of Assent Form (i.e., Cover Letter or Verbal Script), or Waiver.

Attachments Section

*** * * HIPAA * * ***

14. Health Insurance Portability Accountability Act (HIPAA)

To determine if data for this project is covered by HIPAA, respond to the four questions below.

1. Will health information be obtained from a covered entity, known as a clearinghouse, such as Blue Cross, that processes or facilitates processing health data from another entity, including but not limited to state databases? N

2. Will the study involve the provision of healthcare by a covered entity, such as the UCD Medical Center? N

3. If the study involves the provision of healthcare, will a health insurer or billing agency be contacted for billing or eligibility? N
4. Will the study involve other HIPAA criteria not listed above? N

If you answered "YES" to any of the questions above, you are subject to HIPAA and must complete a HIPAA authorization or waiver request with your protocol.

Use table below ONLY when requesting waiver/alteration of HIPAA authorization.

Protocol Title: Longitudinal Study of Hospital Outcomes for California's Children

Attachments Section

*** * * Assurance of Consistency * * ***

15. Assurance of Consistency between Grant Application and CPHS Protocol

Is this project funded by a grant? N

If 'Yes' is checked, please attach only the sections of the grant application, in Attachments, that address the questions below. List the page(s) in the grant application that confirm the consistency with the protocol. Also include that section, such as Subject Population, in the Protocol Information that confirms the consistency with the grant application. This section does not apply to contracts.

a) The title of the project in the grant application and the research protocol are the same. If not explain why.

b) The specific aims of the project in the grant application and the research protocol are the same. If not, explain why. Please include the page number(s) where this information may be found on both documents.

c) The research design/methods are the same in the grant application and the research protocol. If not, explain why.Please include the page number(s) were this information may be found on both documents.

d) The inclusion criteria are the same in the grant application and the research protocol. If not, explain why. Please include the page number(s) were this information may be found on both documents.

e) The human subjects protections, including vulnerable populations, are the same in the grant application and the research protocol. If not, explain why. Please include the page number(s) were this information may be found on both documents.

*** * * Attachments * * ***

Attach all documents associated with your project.

Document Type	Document Name	Attached Date	Submitted Date
Approval Documentation from External IRB	OLIVA_13-02-1077_2013iRIS_Outcome_Letter	02/26/2013	02/28/2013
Approval Documentation from External IRB	OLIVA_13-02-1077_2013iRIS_ Study Application	02/26/2013	02/28/2013

Protocol Title: Longitudinal Study of Hospital Outcomes for California's Children

Approval Documentation from External IRB	OLIVA_13-02-1077_2013iRIS_ Study Summary	02/26/2013	02/28/2013
Budget	OLIVA_13-02-1077_Contract Budget 12-13 12.10.10	02/26/2013	02/28/2013
Budget	OLIVA_13-02-1077_Contract Budget 13-14 12.10.10	02/26/2013	02/28/2013
Curriculum Vitae of Principal Investigator	OLIVA_13-02-1077_CV	02/26/2013	02/28/2013
Curriculum Vitae of the Co-Principal Investigator	OLIVA_13-02-1077_REMY_CV	02/26/2013	02/28/2013
Data Security Requirements Letter	OLIVA_13-02-1077_DATA_SECURITY_LETTER	02/26/2013	02/28/2013
Cover Letter	Oliva_13-02-1077_covlet	02/26/2013	02/28/2013
Form: Annual Report for CA Information Practices Act	OLIVA_13-02-1077_AnnReviewFormIPA	02/26/2013	02/28/2013
Protocol: Last Approved	OLIVA_13-02-1077_2012CPHS_PROTOCOL_20070319	02/26/2013	02/28/2013
Protocol: Last Approved	OLIVA_13-02-1077_2012CPHS_APPENDIX_PAGES	02/26/2013	02/28/2013
List of study variables	OLIVA_13-02-1077_Variables_PDD_2010-07-20	02/26/2013	02/28/2013
List of study variables	OLIVA_13-02-1077_VariablesNONPUBLIC_ ED_AS_2010-10-05	02/26/2013	02/28/2013
OSHPD Pre-Approval Letter	OLIVA_13-02-1077_OSHPD_LETTER	02/28/2013	02/28/2013
List of study variables	OLIVA_13-02-1077_VARIABLES_FD	02/28/2013	02/28/2013
List of study variables	OLIVA_13-02-1077_VARIABLES_DT	02/28/2013	02/28/2013
List of study variables	OLIVA_13-02-1077_VARIABLES_BC	02/28/2013	02/28/2013
CPHS Memorandum	CPHS - Important Memo - Approval Letter Language	12/13/2013	02/27/2014
Approval Documentation from External IRB	OLIVA_13-02-1077_IRIS_CHR_MODIFICATION_FORM_20141229	02/23/2015	02/24/2015
Approval Documentation from External IRB	OLIVA_13-02-1077_IRIS_CHR_Form_20150108	02/23/2015	02/24/2015

Protocol Title: Longitudinal Study of Hospital Outcomes for California's Children

---2---

Approval Documentation from External IRB	OLIVA_13-02-1077_IRIS_Outcome_Letter_20150113	02/23/2015	02/24/2015
Budget	OLIVA_13-02-1077_MCAH_Budget_2014-2015	02/23/2015	02/24/2015
Budget	OLIVA_13-02-1077_MCAH_Budget_2015-2016	02/23/2015	02/24/2015
Cover Letter	OLIVA_13-02-1077_COV_LET_20150225	02/23/2015	02/24/2015
Curriculum Vitae of the Co-Principal Investigator	OLIVA_13-02-1077_RIENKS_CV	02/23/2015	02/24/2015
Data Security Requirements Letter	OLIVA_13-02-1077_DATA_SECURITY_LETTER_20150225	02/23/2015	02/24/2015
Publications	OLIVA_13-02-1077_REMY_2014_WILLITS	02/23/2015	02/24/2015
OSHPD Pre-Approval Letter	OLIVA_13-02-1077_OSHPD_APPROVAL_20140415	02/23/2015	02/24/2015
Data Security Requirements Letter	OLIVA_13-02-1077_DATA_SECURITY LETTER_20150311	03/16/2015	03/16/2015
Data Security Requirements Letter	OLIVA_13-02-1077_CHPS_UCSF_IT_OFFICER_20150309	03/16/2015	03/16/2015

---

* * * Obligations * * *

Obligations (Researcher's Responsibilities)

The Principal Investigator is ultimately responsible for the conduct of the project. Obligations of the Principal Investigator include:

Conduct the research involving human subjects as presented in the protocol, including modifications, as approved by the Department and Institutional Review Board. Changes in any aspect of the study (for example project design, procedures, consent forms, advertising materials, additional key personnel or subject population) will be submitted to the IRB for approval before instituting the changes (PI will submit the "Amendment/Revision" form);

Provide all subjects a copy of the signed consent form, if applicable. Investigators are required to retain signed consent documents for three (3) years after close of the study;

Protocol Title: Longitudinal Study of Hospital Outcomes for California's Children

---2---

Submit either the "Protocol Deviation Form" or the "Report Form" to report protocol Deviations/Violations, Unanticipated Problems and Adverse Events that occur in the course of the protocol. Any of these events must be reported to the IRB as soon as possible, but not later than five (5) working days;

Submit the "Continuing Review" Form in order to maintain active status of the approved protocol. The form must be submitted annually at least four (4) weeks prior to expiration, five (5) weeks for protocols that require full review. If the protocol is not renewed before expiration, all activities must cease until the protocol has been re-reviewed;

Certify that all members of the study team have answered the financial interests question and only those individuals listed in section 8 above have disclosed any financial interest related to this study.

Adhere to federal, state and OSHPD policies regarding the rights and welfare of human participants participating in this study.

Comply with and be bound by the U.S. DHHS regulations for the protection of human subjects and relevant ethical principles.

Comply with and be bound by all decisions of the California Health and Human Services Agency Committee for the Protection of Human Subjects.

X The Principal Investigator has read and agrees to abide by the above obligations.
X The Co-Principal Investigator has read and agrees to abide by the above obligations.
X The Responsible Official has read and agrees to abide by the above obligations.

*** * * Event History * * ***

Event History

Date	Status	View Attachments Letters
02/07/2013	NEW FORM CREATED	
02/28/2013	NEW FORM SUBMITTED	Y
03/01/2013	NEW FORM RETURNED	
03/01/2013	NEW FORM RESUBMITTED	Y

Protocol Title: Longitudinal Study of Hospital Outcomes for California's Children

03/04/2013 NEW FORM PANEL ASSIGNED
03/08/2013 NEW FORM REVIEWER(S) ASSIGNED
04/08/2013 NEW FORM APPROVED Y Y
02/25/2014 CONTINUING REVIEW 1 FORM CREATED
02/27/2014 CONTINUING REVIEW 1 Y
FORM SUBMITTED
02/27/2014 CONTINUING REVIEW 1 FORM RETURNED
02/27/2014 CONTINUING REVIEW 1 Y
FORM RESUBMITTED
02/27/2014 CONTINUING REVIEW 1 FORM REVIEWER(S) ASSIGNED
03/06/2014 CONTINUING REVIEW 1 Y
FORM SUBMITTED (CYCLE 1)
03/07/2014 CONTINUING REVIEW 1 Y
FORM SUBMITTED (CYCLE 2)
04/04/2014 CONTINUING REVIEW 1 Y Y FORM APPROVED
02/02/2015 AMENDMENT 1 FORM CREATED
02/23/2015 AMENDMENT 1 FORM DELETED
02/23/2015 CONTINUING REVIEW 2 FORM CREATED
02/24/2015 CONTINUING REVIEW 2 Y
FORM SUBMITTED
02/25/2015 CONTINUING REVIEW 2 FORM RETURNED
02/25/2015 CONTINUING REVIEW 2 Y
FORM RESUBMITTED
02/25/2015 CONTINUING REVIEW 2 FORM REVIEWER(S) ASSIGNED
03/09/2015 CONTINUING REVIEW 2 Y
FORM SUBMITTED (CYCLE 1)
03/12/2015 CONTINUING REVIEW 2 Y
FORM SUBMITTED (CYCLE 2)
03/16/2015 CONTINUING REVIEW 2 Y
FORM SUBMITTED (CYCLE 3)

Protocol Title: Longitudinal Study of Hospital Outcomes for California's Children

---2---

04/06/2015 CONTINUING REVIEW 2 Y Y FORM APPROVED
02/10/2016 CONTINUING REVIEW 3 FORM CREATED
03/02/2016 CONTINUING REVIEW 3 Y
FORM SUBMITTED
03/03/2016 CONTINUING REVIEW 3 FORM RETURNED
03/03/2016 CONTINUING REVIEW 3 Y
FORM RESUBMITTED
03/04/2016 CONTINUING REVIEW 3 FORM REVIEWER(S) ASSIGNED
04/01/2016 CONTINUING REVIEW 3 Y Y FORM APPROVED