CENTER FOR DATA INSIGHTS AND INNOVATION
CALIFORNIA HEALTH & HUMAN SERVICES AGENCY

View xForm - Project Application v6

This form is for new projects that have not been previously approved by CPHS.

Data entry
- Submitted 06/30/2026 7:37 PM ET by Ann Hamilton, PhD

New Submission Study Personnel

NEW CONTACT INSTRUCTIONS

If personnel are not found by their email address while trying to complete the following questions, you can add them in the system with the link below. Click on the "New Contact Form" and complete it. Within a few minutes of completing the form, you will receive an email notifying you of the availability of the new contact. You should then be able to add them in the subsequent questions.

User had the option to start a different form here.

PRINCIPAL INVESTIGATOR (PI)

Enter the Principal Investigator's email address.

Ann Hamilton, PhD

Email: ahamilt@med.usc.edu **Business:** (323) 865-0434

Choose the institution with which the PI is affiliated (not the location at which the research is being conducted).

Keck School of Medicine

Enter the city in which the PI's institution is located.
Los Angeles

Enter the state in which the PI's institution is located.

Start typing in the state name to select the name from the list.

California

Attach a copy of the PI's Curriculum Vitae.

HamiltonCV-May2026.docx PI Curriculum Vitae

CO-PRINCIPAL INVESTIGATOR (CO-PI)

Enter the Co-PI's email address by clicking on the "Add Contact" button.

If there are multiple co-principal investigators, repeat this action for all Co-PIs. If there are no Co-PIs for this project, skip this question.

Megan Haymart, MD

Email: meganhay@med.umich.edu **Business:** (734) 615-6745

Attach a copy of each Co-PI's Curriculum Vitae.

HaymartCV-5.19.26.docx Co-PI Curriculum Vitae

ADMINISTRATIVE CONTACT

Enter the email address(es) for the administrative contact(s). If you are the administrative contact, enter your email address, and enter anyone else you want listed as an administrative contact.

Yesenia Carranza

Email: yesenia.carranza@med.usc.edu **Business:** (323) 319-7051

RESPONSIBLE OFFICIAL (RO)

Enter the RO's email address.

*The RO **cannot** be the same person as the PI or Co-PI. The RO must have supervisory authority, in the administrative structure of the institution, over the PI.*

Ricky Bluthenthal, BA, MA, PhD

Email: ricky.bluthenthal@med.usc.edu **Business:** (323) 442-8236

OTHER RESEARCH STAFF

Enter the email address for any other research staff by clicking the "Add Contact" button.

Repeat this action for all other research staff not previously provided on this screen that should receive notifications about this project. If there are no additional research staff, skip this question.

Yesenia Carranza
Email: yesenia.carranza@med.usc.edu **Business:** (323) 319-7051

Dustin Tan, BPH
Email: dustinta@usc.edu **Mobile:** (323) 442-0759

Danidza Virginia Parker
Email: Danidza.Parker@med.usc.edu **Business:** (323) 271-8153

Check for PI same as RO (internal only question) *(Internal)*

False

Project Information

SUBMITTER

Application completed by:

Ann Hamilton, PhD
Email: ahamilt@med.usc.edu **Business:** (323) 865-0434

PREVIOUSLY APPROVED EXEMPTION

Is there a previously-approved exemption from CPHS for this project?

No

PROJECT TITLE

Enter the project title (please capitalize each word in your title).

RISK-STRATIFIED CARE FOR THYROID CANCER SURVIVORS

PROJECT SITE

Indicate the primary site at which the research will be conducted.

Keck School of Medicine

STUDY PROCEDURES

Indicate the study procedures involved in this research. Check all that apply.

Data Registry
Recruitment-Participant
Surveillance Data
Surveys

TYPE OF RESEARCH REQUEST

Indicate which of the following applies to this research. Check all that apply.

*Death Data Only refers to health-related studies requesting existing mortality data from **within** the California Human Health Services Agency (CHHSA)*

*SB-13 (Information Practices Act) refers to health-related studies requesting existing data from **outside** the CHHSA (e.g. California Department of Corrections and Rehabilitation [CDCR], California Department of Education [CDE], etc.) **OR** studies requesting data **within** the CHHSA that are not state funded or involving state staff.*

Common Rule/Human Subjects refers to health-related studies that involve direct or indirect interaction with human subjects (e.g. recruitment, interviews, etc.)

*Common Rule Only refers to health-related studies requesting existing data from **within** the CHHSA (e.g. Office of Statewide Health Planning and Development [OSHPD], California Department of Public Health [CDPH], etc)*

Common rule/Human subjects

PROJECT TYPE DETAILS

Indicate which, if any, apply to this research. Check all that apply.

If the research does not involve any of following, choose "None of the above."

Minimal Risk
Non-English translation required
Consent form

VULNERABLE POPULATIONS

Indicate which vulnerable populations, if any, will be involved with this research. Check all that apply.

If vulnerable populations are not part of the research, choose "Not applicable."
Note regarding 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.

Not applicable

FUNDING

Is this research funded?

Yes

Indicate the funding source for this project.
Federally funded
University funded

Enter name of federally-funded source.
NCI

EXPEDITED REVIEW CONSIDERATION

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, choose 'not applicable'; your protocol will be reviewed by the full committee. Note that CPHS will make the final determination of whether the project meets the criteria for expedited review.

Protected Health Information/Personally Identifiable Data (PHI/PID) is defined as information in any format that identifies the individual, including demographic information collected from an individual that can reasonably be used to identify the individual. Additionally, PHI is information created or received by a healthcare provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual, including any of the 18 HIPAA identifiers.

Note: Please be aware that individual participants may be identifiable by combining other items in the data even when none of the 18 HIPAA identifiers are present. Thus, a study may still contain PID even after removing or never acquiring the identifiers, and the investigator may still need to provide complete answers for the data security questions in the protocol.

***The Departments within the California Health and Human Services Agency (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 and Statewide Health Planning and Development.*

Not applicable

ANTICIPATED PROJECT START DATE

Projects cannot begin before they have been reviewed. The earliest possible start date is always the date of the next public meeting at which the project will be heard.

For a list of public meeting dates, see the CPHS website

08/03/2026

ANTICIPATED PROJECT END DATE

03/31/2029

Project Details

PURPOSE

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.

Thyroid cancer remains understudied despite being the 3rd most common cancer among female cancer survivors, having the 2nd highest cancer incidence in Hispanic and Asian/Pacific Islander women, and being the most common cancer in young adults ages 18-33. There has been an increase in the number of thyroid cancer survivors due to rising thyroid cancer incidence and young age at diagnosis. Unfortunately, there are a substantial number of thyroid cancer survivors who were likely cured of their thyroid cancer with initial treatment, but because of limited data, they continue cancer surveillance for many years, often lifelong and experience years of cancer-related worry, additional testing leading to false positive results, and in some instances complications and side-effects secondary to unnecessary treatments. The lack of evidence-based, risk-stratified thyroid cancer surveillance care strategies is largely driven by an insufficient understanding of recurrence risk. This study is designed to assess recurrence risk in two cohorts of thyroid cancer survivors. The Phase 1 cohort was initially surveyed in 2017 and the original protocol was approved under the USC protocol HS-16-00646 (Hamilton, PI) and the CPHS protocol (16-10-2766). The USC IRB reviewed and approved the recontact of the 1248 thyroid cancer survivors who participated in 2017 (and who provided their contact information at that time) under a new protocol (UP-25-00068) and cancer registry data was not required for recontacting them. The patient survey and most of the recruitment documents approved by the USC IRB for Phase 1 will be applied to the Phase 2 cohort of more recently diagnosed cases (2018-19) that are being selected at this time. These will include 900 new cases to determine more recent experience of surveillance and recurrence. For both cohorts, telephone follow-up and remailings of survey packets will be performed in order to increase response rates. A second mailing will be sent to survey respondents to ask them to sign a HIPAA form to review medical records. An abstract form will be sent to providers to obtain information on surveillance and recurrence. In addition subsequent path reports from both cohorts will be reviewed to determine progression or recurrence. The overall PI of the study is Megan Haymart, MD from the U. of Michigan. De-identified research files will be provided to Dr. Haymart for analyses to be conducted. She is included as a co-PI on the project.

MAJOR RESEARCH QUESTION

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

Specific Aim 1: To develop, evaluate, and validate a model that predicts recurrence risk for thyroid cancer patients.
Specific Aim 2: To define appropriate risk-stratified surveillance care pathways
Specific Aim 3: To determine the net benefit of recurrence risk-stratified surveillance by incorporating trade-offs such as false positive image findings, treatment-related side effects, worry, symptom burden, quality of life, and cost.

STUDY PROCEDURES

Describe in detail all procedures for this research. Do not attach grant applications or similar documents. Information in this application must be sufficient to fully explain the procedures without such documents

For Phase 2, 900 thyroid cancer cases diagnosed in 2018-19 will be selected from the Los Angeles County Cancer Registry. We will first send them a patient survey to complete that will include a postage paid envelope for return or they may complete the survey online. Two weeks after mailing, if no response, follow-up efforts will include 5 calls at different days, times of the day, and weekends. In addition we will send a reminder letter, reminder packets, and additional follow-up calls will be made after these mailings. After receiving a completed survey, a second request will be made to ask them to sign an Informed Consent, list doctors and providers where they have received care, and sign a HIPAA form to allow review of their medical records related to their thyroid cancer care. The survey is estimated to take 30 minutes and the HIPAA form mailing is estimated to take 15 minutes. The researcher will not be present when the participant is completing these tasks since they will be receiving correspondence by mail and can complete the requests at their convenience. Once the HIPAA form is received we will contact their physicians to ask them to complete an abstract form regarding their thyroid cancer treatment and surveillance. In addition we will review subsequent path reports received by the Cancer Registry to identify progression of disease. After approval of the study, we will submit an amendment to obtain vital statistics data to determine survival at the end of the grant period. We also with to review subsequent path reports for the Phase 1 cohort.

Please upload here any tables or charts related to your study procedures and any materials (such as surveys or interview questions) that will be presented to participants.

clinician data collection form 8-14-25.docx	Other Documents
Certification of Translation Accuracy.pdf	Questionnaires
Haymart new R01 survey FINAL 1.27.24_ES_7182025-Spanish.pdf	Questionnaires
Haymart new R01 survey FINAL 11.22.24.pdf	Questionnaires

RECORDING

Will audio or video recording occur?

No

DECEPTION

Will deception be used in this study?

No

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY (CHHSA) DEPARTMENTS LIST

Indicate any of the following CHHSA department(s)' involvement in providing research staff, funding and/or patients from State mental hospitals for this project.

CDPH: Department of Public Health

STATE DEPARTMENT DATA/SPECIMENS

Choose the department(s) from which you are requesting data and/or specimens and provide the formal name of the database or specimen registry. After you have selected the department from the drop down and entered the formal name of the database or specimen registry, click 'add' and repeat to add additional data and/or specimens if applicable.

Agency	Provide the formal name of the data base or specimen registry.
California Department of Public Health	California Cancer Registry

Study Population

POPULATION DESCRIPTION

Provide a full description of how human subjects will be involved in the research. Address characteristics of subjects such as: age; sex; ethnicity; and number of participants. Include requested participant number.

The 900 Los Angeles County cases for Phase 2 will be thyroid cancer patients diagnosed in 2018-2019 who were aged = 18 years at the time of thyroid cancer diagnosis, with differentiated thyroid cancer (papillary, follicular, or oncocytic carcinoma). 50% of the cases will be selected from those who underwent less intensive surgical treatment, i.e., lobectomy (surgical codes B250--B253). Sex and race will be selected at random. These cases will be asked to complete a survey and sign a HIPAA form to allow review of medical records.

There is a Phase 1 cohort of 1248 cases diagnosed in 2014-15 who participated in a previous study. For them we have already received USC IRB approval for this follow-up study, but would now like to update cancer registry variables, review path reports, and link doctors to the MD database to contact them to obtain medical records (for those who have signed the HIPAA form).

DATABASE DETAILS

List the database(s) to be used and the time period(s) being requested. This may include requests for future data that is not available at this time.

List the variables being requested, including a brief description of each variable.
Justify the need for each variable and for the quantity of data being requested.
You may also attach a list of variables on the next question.

Also address if participants will be involved in any other studies.

For the Phase 2 cohort we will select cases from the Los Angeles County Cancer Surveillance System. Cancer registry variables related to the selected cases' demographic, clinical, and treatment related characteristics will be included as well as the patient identifiers needed to recruit the patients and physician and hospital ID numbers needed to request medical records. We will link the physician IDs to the MD database to obtain physician contact information.
For the Phase 1 cohort, we want to update the cases' registry variables with these listed variables, review path reports, and obtain physician IDs and MD database information to use to contact their physicians.

If you have a list of variables with the details requested in the above question, attach that here. If you provided all details on the database in the question above, skip this question.

Reviewed_Hamilton_Requested_Variables-AH edits.xlsx List of Variables

Deleted Attachments: 3 (Most Recent: Registry_VariablesNoVS.docx on 06/23/2026 1:20 AM ET)

RATIONALE

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

We need to study a population based sample of thyroid cancer cancer cases selected at two different time points to assess changes in surveillance and progression to advanced disease among thyroid cancer cases.

RECRUITMENT DETAILS

Describe how potential subjects will be identified for recruitment. Examples include: class rosters; group membership; individuals answering an advertisement; organization position titles (e.g., 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.)?

Important to remember: subjects cannot be contacted before IRB approval.

The subjects for Phase 2 will be identified from the Los Angeles Cancer Surveillance Program based on their cancer site (thyroid), date of diagnosis (2018-19), age (18+), and histology, with oversampling of those with lobectomy or no surgery. They will learn about the research by receiving an introductory letter, cancer registry brochure, information sheet, copy of paper survey, and return envelope. They will be asked to complete the survey and return it by mail when convenient, or they may do it online. Upon receipt of their survey, a second mailing will be sent to request their signature on a HIPAA form to allow us to review their medical records. We will ask them to list the doctors and facilities where they have received care. We also will obtain the physician IDs from the cancer registry for those providers who treated them when they were diagnosed. Physicians will be sent a letter, study brochure, list of patients, and abstract form to complete.

Attach copies of all recruitment materials.

California39s-Cancer-Reporting-System-Spanish.pdf	Recruitment Materials
CCR English research brochure.pdf	Recruitment Materials
Clinician Intro Letter 8-14-25.doc	Recruitment Materials
FORM B Doctor and Provider Form.docx	Recruitment Materials
HIPAA Intro letter 8-14-25.docx (1).doc	Recruitment Materials
HIPAA Intro letter_ES442026.docx	Recruitment Materials
HIPAA Reminder letter 2-23-26.doc	Recruitment Materials
HIPAA Reminder letter 2-23-26_ES_final442026.docx	Recruitment Materials
PatientInfoFormThyroidStudy8-14-2025.docx	Recruitment Materials
Phase 2survey call script - USC- ES_632026.docx	Recruitment Materials
Phase-2Introductory Letter USC 5-26-26.docx	Recruitment Materials

Phase-2Introductory Letter USC_v2_ES_632026.docx	Recruitment Materials
Phase-2Reminder Letter USC_1-22-2025_ES.docx	Recruitment Materials
Phase-2Reminder Letter USC_5-27-26.docx	Recruitment Materials
survey call script - Phase 2 USC-5-27-26.doc	Recruitment Materials
survey email invite-remind - USC-1-21-25.docx	Recruitment Materials
survey email invite-remind - USC-1-21-25_ES.docx	Recruitment Materials
USC ThyCARE brochure.pdf	Recruitment Materials

SCREENING

Will subjects be screened prior to entry into the research?

No

COMPENSATION

Will subjects be compensated for participating in the study?

Yes

Compensation type
Gift card

Explain the amount and schedule of compensation that will be paid for participation in the study. Include provisions for prorating payment. The amount should not be coercive.
Participants will receive a $20 gift card up front with the survey mailing, and a $10 gift card upfront with the HIPAA mailing. The gift cards are for the participant to keep whether or not they complete the survey or the HIPAA form.

STUDY DURATION

Estimate the probable duration of the entire study. This estimate should include the total time each subject is to be involved and the duration of each data collection about the subject.

E.G., This is a two-year study. Participants will be interviewed three times per year; each interview will last approximately two hours. Total approximate time commitment for participants is 12 hours.

The participants are asked to complete a survey that is estimated to take 30 minutes and to sign a HIPAA form that is estimated to take 15 minutes.

Risks and Benefits

RISK DESCRIPTION

Provide a description of possible risks to participants: physical, psychological, social, economic, loss of data security, and/or loss of confidentiality. Describe and justify whether the research is minimal risk or greater than minimal risk.

Risks for completing the survey include possible loss of confidentiality and possible psychological stress in completing questions about their cancer treatment and it's impact on their quality of life. However they are instructed to skip any question that they do not want to answer.
Other risks associated with linkage of data from the cancer registry, providers and hospitals and path reports are minimal because all data are kept confidential and all data sources will be linked by a study id and no personal identifiers will be kept in analytic files. The greatest potential risk is loss of confidentiality related to personal health information

MEDICAL SERVICE RISKS

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 that clearly.

No medical services are provided.

INTERNATIONAL RESEARCH

Will this research occur outside of the United States or U.S. territories?

Check with client to see if they consider territories to be outside the U.S. or not, as this can vary between institutions.

No

LESS RISKY METHODS

Describe any less risky methods and why they are not being used.

The study will only involve a patient survey that can be completed when convenient for the patient. They can skip any question they do not wish to answer. Thus this is a minimal risk study. The data obtained from medical records will be kept confidential and no identifiers will be included in research files. Thus the risk of loss of confidential information is minimal.

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, state that clearly.

There are no direct benefits to the subjects other than the knowledge that they have contributed to research that may help thyroid cancer cases diagnosed in the future and could contribute to improving treatment and quality of life of other cancer survivors.

JUSTIFICATION OF RISKS

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

The study risks due to loss of confidentiality and psychological stress are minimal compared to the
information to be gained from the study

Adminstrative Safeguards

PERSONALLY IDENTIFIABLE DATA (PID) INSTRUCTIONS

Protected Health Information/Personally Identifiable Data (PHI/PID) is defined as information in any format that identifies the individual, including demographic information collected from an individual that can reasonably be used to identify the individual. Additionally, PHI is information created or received by a healthcare provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual, including any of the 18 HIPAA identifiers.

Note: Please be aware that individual participants may be identifiable by combining other items in the data even when none of the 18 HIPAA identifiers are present. Thus, a study may still contain PID even after removing or never acquiring the identifiers, and the investigator may still need to provide complete answers for the data security questions in the protocol.

If the researcher demonstrates that he or she is unable to comply with any of the requirements below, he or she may request an exception from these requirements. The researcher should indicate any measures that will be taken to address this requirement. The exception request should be made in the text box of the corresponding requirement. An exception will only be granted if the researcher can demonstrate that adequate alternative measures have been taken to minimize risks so as to justify the exception.

HIPAA IDENTIFIERS

Please identify which HIPAA Identifiers you plan to request as part of your submission.

Name
Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)
All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)
Telephone numbers
Social Security Number
Medical record number

TRAINING PROCEDURES

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.

Staff are required to have IRB and HIPAA certification to participate in the study. They also take confidentiality training administered by the Los Angeles Cancer Surveillance Program and sign confidentiality pledges.

STAFF VETTING PROCEDURES

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

All employees hired by USC undergo a background check.

SUPPORT LETTER

Obtain and submit a department support/data release letter.

This is a statement from the state agency or department you are receiving data from. It must be on that agency's/department's letterhead and should include both

1) *that the release of the desired data is legal and*

2) *that the entity is willing to release the desired data to you, the researcher. If you are not receiving data, this letter should indicate that you are supported.*

***For VSAC requests, if you do not have a Departmental Letter of Support (LOS)/Data Release, you may upload a copy of the Data Request Form (application) from the department to secure a review for the upcoming cycle. The protocol will not be approved until the LOS is uploaded to the protocol.*

Please also review the CPHS Statement for Birth and Death Data.

CPHS_LOS_Hamilton, Ann.docx.pdf Department Letter of Support

Deleted Attachments: 1 (Most Recent: CPHS_LOS_Hamilton, A.docx.pdf on 06/30/2026 3:20 PM ET)

PREVENTING RE-USE AND UNAUTHORIZED ACCESS

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.

All data will be kept on secure servers and not released to any unauthorized person or entity. Dr. Hamilton will assure that she will not release data for any other purpose by signing the CCR's DUA. Dr. Haymart will also sign the CCR's DUA.

CONFIDENTIALITY OF PUBLISHED DATA

Indicate whether information will be published that could possibly be used to identify an individual subject.

No publications will include individual's names or allow for identification of an individual. All results will be presented in tabular fashion.

DATA REQUEST JUSTIFICATION

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?

We have assessed the number of cases required to meet the study's goals. The sample selection and power of the study were reviewed by NCI as part of the grant review process.

LIMITATIONS TO DATA ACCESS

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

Access is limited to only staff who need to select the cases according to the eligibility criteria and to implement the research.

UNIQUE IDENTIFIERS

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

SSN's will only be used to trace lost individuals. The sources for tracing (Lexus Nexus) use SSNs to provide updated addresses from their databases. Without using them we may obtain addresses to the wrong individual (e.g. someone with the same name).

PROTECTION AGAINST SMALL CELL SIZES AND ASSOCIATED PROBLEMS

Describe 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.

Cell sizes under 5 cases will be suppressed in any publication.

LINKAGES

Will the data set be linked with any other data sets?

No

DESTRUCTION OF PID VERIFICATION

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.

Yes

DATA SECURITY LETTER

Upload a certification/statement from the Chief Information Officer, Privacy Officer, Security Officer or equivalent position of the researcher's institution that CPHS Data Security Standards are met.

- *Data security letters cannot be signed by the Principal Investigator or Responsible Official.*
- *The data security letter must be on your institution's letterhead.*
- *Example of data security letter*

Ann Hamilton - Risk-Stratified Care for Thyroid Cancer Survivors.pdf	Data Security Letter

Deleted Attachments: 1 (Most Recent: Ann Hamilton - Survivorship for early onset colorectal cancer (002).pdf on 06/30/2026 3:23 PM ET)

Physical Safeguards

DATA PROTECTION

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.

Yes

DATA DESTRUCTION

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

Yes

RETAINED DATA

Will the retained data/samples have personal identifiers or be de-identified?

data will contain personal identifiers

DESTRUCTION METHODS

Describe how you will ensure the PID in paper form is disposed of through confidential means, such as cross cut shredding or pulverizing.

Cross cut shredding

FAXING

Describe how you will ensure that faxes with PID are not left unattended and fax machines are in secure areas.

FAX machines are in secure areas. We will use sfax, an electronic method of faxing requests to providers, thus paper copies will not be required. Any faxes with PID will not be left unattended. Computers are password protected

MAILING

Indicate whether mailings of PID are sealed and secured from inappropriate viewing; and whether mailings of 500 or 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.

Any mailing of PID to request medical records would be sealed and protected, marked as confidential, and sent with a tracking number. There would be no mailings of 500 or more of individually identifiable records of PID.

ELECTRONIC STORAGE

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 ever be left unattended in cars or other unsecured locations.

Any PID on paper or electronic form stored on laptop computers or portable electronic storage media will never be left unattended to cars or other unsecured locations.

PHYSICAL STORAGE

Describe whether facilities, which store PID in paper or electronic form, have controlled access procedures, and 24 hour guard or monitored alarm service.

All facilities which store PID in paper or electronic form at USC are protected by controlled access procedures and have necessary protection as required.

SERVER SECURITY

Provide a description of whether all servers containing unencrypted PID are housed in a secure room with controlled access procedures.

All servers at USC are protected by controlled access procedures and have necessary protection as required.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

Identifiers will be stored separately from analysis data. With regard to retaining data with personal identifiers, in Los Angeles, a file that links personal identifiers to the study id will be maintained in order to link these cases to mortality data to be obtained later. These identifiers would include name, date of birth, and registry Patient ID and Study ID. This cross walk file would be maintained at USC for up to 10 years to allow for longer term follow-up. However, in the research database that Dr. Haymart (U of Mich) will have access to for analysis, no personal identifiers will be included.

DISK STORAGE

State whether all disks with PID will be destroyed.

All disks with PID will be destroyed.

Electronic Safeguard

COMPUTER ACCESS OVERVIEW

State whether all computer access will be protected through the use of encryption, passwords, and other protections.

All computer access is protected through use of encryption, passwords and other protections.

FIPS 140-2 COMPLIANCE: WORKSTATIONS

Indicate whether all workstations that contain PID have full disc encryption that uses FIPS 140-2 compliant software. If not, explain why not and what encryption will be used.

Yes all workstations have full disc encryption that uses FIPS 140-2 compliant software.

FIPS 140-2 COMPLIANCE: LAPTOPS

Indicate if all laptops that contain PID have full disc encryption that uses FIPS 140-2 compliant software. If not, explain why not and what encryption will be used.

Yes all laptops have full disc encryption that uses FIPS 140-2 compliant software.

FIPS 140-2 COMPLIANCE: REMOVABLE MEDIA DEVICES

Indicate if PID on removable media devices (e.g. USB thumb drives, CD/DVD, smartphones, backup recordings) are encrypted with software that is FIPS 140-2 compliant.

Yes all removable media devices have full disc encryption that uses FIPS 140-2 compliant software.

SECURITY PATCHES

Indicate if all workstations, laptops and other systems that process and/or store PID have security patches applied in a reasonable time frame.

Yes, all workstations and laptops are updated daily with security software.

PASSWORD CONTROLS

Indicate if sufficiently strong password controls are in place to protect PID stored on workstations, laptops, servers, and removable media.

Yes sufficiently strong passwords are in place and are required to be changed on regular basis.

ELECTRONIC SECURITY CONTROLS

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.

Yes, these security controls are in place.

FIPS 140-2 COMPLIANCE: ELECTRONIC TRANSMISSION

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.

PID will not be transmitted outside the secure internal network.

INTERNET ACCESSIBILITY

Note if PID in an electronic form will be accessible to the internet.

PID in electronic form will not be accessible to the internet

DISPOSING OF PID

When disposing of electronic PID, indicate whether sufficiently secure wiping, degaussing, or physical destruction will be used.

Yes, physical destruction or sufficiently secure wiping will be used.

Conflict of Interest Information

CONFLICT OF INTEREST (COI) INSTRUCTIONS

A COI is defined as 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. Researchers must disclose any COI, including perceived COI.

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 connection 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.**

DISCLOSURES

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 above-referenced project?

No

Informed Consent Procedures

INFORMED CONSENT PROCEDURES

Provide a description of procedures to be used in obtaining and documenting informed consent from participants.

See instructions and examples on CPHS website.

For the survey we have included an Informed Consent for Research Document that includes the elements of an informed consent. The participant is told that by completing and sending back the survey they are consenting to participate. They will be receiving the materials in their own home and can make the decision if they wish to participate at any time they choose. They are provided with PI and study coordinator phone numbers to call if they have questions. We will be providing a Spanish translation and the translator certificate in another amendment.
For the HIPAA request, a second mailing will include and Informed Consent booklet that will include an Informed Consent for signature, a form to list doctors and providers seen for their thyroid cancer care, and a HIPAA form for their signature. They can review and complete these documents at any time at home after they receive them. PI and study coordinator phone numbers are provided if they have any questions. Also interviewers will be calling participants to see if they had any questions.

CONSENT FORMS

Attach copies of consent forms and any other documents or oral scripts used to inform potential research subjects about the study. See examples of consent and assent forms on the CPHS website.

Be sure to include a concise explanation of key information for participants at the beginning of your consent form, as shown in the examples on the website. Also attach the Participant's Bill of Rights (download the revised version from the same CPHS website). 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, attach a document that explains how all of the criteria below will be satisfied.

Informed Consent for Research-HIPAA_09-08-2025.pdf	Consent Form
Phase 2Informed Consent_06-22-2026.docx	Consent Form

Deleted Attachments: 2 (Most Recent: Phase 2 Informed Consent_06-22-2026_ES.docx on 06/22/2026 9:43 PM ET)

TRANSLATED DOCUMENTS

Provide copies of the non-English version of consent/assent forms and/or scripts to be used in this research.

Phase 2 Informed Consent_06-22-2026_ES.docx	Consent Form
ThyroidICHIPAASpanishBooklet_6022026.docx	Consent Form

Deleted Attachments: 1 (Most Recent: Phase 1 Informed Consent_05-16-2025-Word_Spanish.pdf on 06/22/2026 9:42 PM ET)

TRANSLATOR

Provide a copy of 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. For studies using documents translated into Spanish, the translation should use formal language.

Certification of Translation Accuracy.pdf	Translator Curriculum Vitae

HIPAA Determination

HIPAA INSTRUCTIONS

To determine if this project is covered by HIPAA, answer the following questions.

COVERED ENTITY

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?

No

HEALTHCARE PROVISIONS

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

No

OTHER HIPAA CRITERIA

Will the study involve other HIPAA criteria not listed above?

Yes

HIPAA WAIVER

Are you requesting a waiver or alteration of HIPAA authorization?

If you have already received a waiver/alteration from another IRB choose 'waiver/alteration approved by another IRB'. You do not need to apply for a waiver or alteration as the HIPAA waiver or alteration of authorization is only required from one IRB.

No

HIPAA AUTHORIZATION FORM

Upload a copy of the HIPAA Authorization form(s) or the documentation of the approval of a waiver/alteration from another IRB.

Booklet with IC Dr and Provider List and HIPAA Thyroid 10-8-2025.pdf	HIPAA Documents

Deleted Attachments: 1 (Most Recent: ThyroidICHIPAASpanishBooklet_6022026.docx on 06/30/2026 7:36 PM ET)

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

Yes

Attach a copy of your project budget here

Copy of Hamilton budget year 3-ah.xlsx Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Cover letter must have the requesting institution's letterhead.

CPHS cover letter Thyroid Study.pdf Cover Letter

To sign this form, enter your IRBManager password. By signing this form, you are indicating that the information within this application is accurate and reflects the proposed research and that you attest to the conflict of interest disclosures for all study team members.

Signed Tuesday, June 30, 2026 7:36:51 PM ET by Ann Hamilton, PhD

In order to submit this form, click "Next" and "Submit." At that time, the application will be routed to the Responsible Official (if this is the first submission) for review and signature.

Calculated Field for agency plus data set *(Internal)*

California Department of Public Health: California Cancer Registry

Responsible Official Signature
- Submitted 07/05/2026 7:44 PM ET by Ricky Bluthenthal, BA, MA, PhD

Responsible Official Signature

After reviewing this application, is it ready for submission to the CPHS IRB?

Yes, ready for submission to IRB.

Enter your password to sign this protocol. By signing this protocol, you are attesting that the information within is accurate and reflects the details of the proposed research project.

Signed Sunday, July 5, 2026 7:44:01 PM ET by Ricky Bluthenthal, BA, MA, PhD

After choosing whether or not the submission is ready for CPHS IRB review, please click "next" and "submit" (on the next screen) to move the form forward to the CPHS IRB or back to the Researcher.

Notify IRB for Pre-Screening

Internal IRB Screening

CPHS Office: The questions on this page will appear every time the project is resubmitted to the CPHS IRB (even after review). Once the project has been reviewed by a committee member, unless researcher has changed questions on the form that impact the level of review, you do not need to update the questions here. If the changes made are not clear and require additional clarification change the 'ready for review' to 'no' and require changes. When you change the answer back to yes, it will remember your previous answers.

Is this study ready to be reviewed by the CPHS panel?

No answer provided.

Copyright ©2000-2026 Tech Software. All Rights Reserved.
2026.7.8575.0/Release/327b5c8 | GCWAWS1 | 2026-07-21 15:08:35Z
Powered By IRBManager