Version: 4.0
Application Version Date: 4/2/2015

Date: Friday, October 09, 2015 4:02:36 PM

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1. Project Identification and Abstract

1.1. * **Type of Submission**:

- (●) **Research Protocol or Study on Human Subjects**
- ( ) Grant/Contract Only
- ( ) Use of Humanitarian Use Device (Not Research)
- ( ) Ceded Review (Utilize approval by an outside IRB)

1.2. * **Full Title of Research Protocol**
Pilot Study for the USC Data Exploration, Warehousing and Archiving for Researchers (DEWARs)

1.3. * **Short Title**
Mini-DEWARS

1.4. **Abstract: Provide a simple explanation of the study and briefly address (in 1 to 2 sentences) each of the following points: rationale; intervention; objectives or purpose; study population or sample characteristics; study methodology; description of study arms (if appropriate); study endpoints or outcomes; follow-up; statistics and plans for analysis.**
Rationale: Use of data across health systems can help patients make better healthcare decisions by providing accurate information about which treatments work, for whom and under what circumstances, and make the research process more safe, effective and efficient.

Objective/Purpose: The objective of the technical and governance infrastructure portion of the project is to create a standardized data warehouse for research that includes coded data from electronic records in a Limited Data Set. Certified researchers beyond this study team will be able to request HIPAA de-identified (safe-harbor) extracts from this Limited Data Set.

In scope for this project:
(1) Create and maintain a data warehouse that contains a HIPAA Limited Data Set
(2) Provide HIPAA Safe-Harbor de-identified data sets extracted from this warehouse for certified investigators agreeing to the terms of use.

In scope for this project but conditional on separate IRBs approval on a case-by-case basis
(1) Any activities requiring re-identification of patients
(2) Any activities requiring extraction of data sets from this warehouse that do not meet safe-harbor criteria.

Methods: We will integrate data from multiple systems into the research data warehouse. Protected health information and personally identifiable information will be retained in a separate repository meeting institutional security standards and PHI will be eliminated to create a data set consistent with HIPAA standards for a limited data set under the attached data use agreement.

After creation, PHI repository will only be accessed on the condition that investigators with IRB approval to re-identify a patient set with HIPAA waivers. Staff on HS-14-00903 will inspect the IRB approval in question to verify that a waiver has been granted.

Interventions and activities: There are no interventions. Activities involve a data harmonization step and running data profiling queries. Investigators on this study will have access to patient level data in a HIPAA-compliant limited data set. Study investigators will respond to queries from USC and CHLA investigators with HIPAA certification criteria. Query -responses- shared with investigators will only contain fully de-identified data accordance with HIPAA safe-harbor criteria. As agreed with Drs. Rose and Spicer, end users receiving query responses with safe harbor data will not be required to seek IRB approval.

Study Population: Unselected sample of patients represented in USC health systems and health systems partnered with USC (e.g. CHLA) will be included in data integration.

Sample/Data Characteristics: Data Infrastructure will support data elements in Electronic Records.

Outcomes: Outcomes will be related to the process of building infrastructure, not human subjects.

1.5. * **Select which IRB you are requesting review from:**
USC-Health Sciences (HSC)

1.6. **To the investigator's knowledge, does the Institution have financial and or intellectual property interests in the sponsor or the products used in this project?** *An institutional conflict may occur when a financial interest of the University has the potential to bias the outcome of research conducted by its employees or students or to create an unacceptable risk to human subjects.*
* ○ Yes ◉ **No**

2. Study Personnel

2.1. * **Study Personnel and their roles:**

	Last Name	First Name	Organization	Study Role	Certifications	Obtain Consent	Interact with Participants	Access Identifiable Data
View	Meeker	Daniella	PREVENTIVE MEDICINE	Principal Investigator	~~HS~~ HIPAA	no		
View	Doctor	Jason	CLINICAL PHARMACY	Co-Investigator	HS HIPAA	no		
View	Kipke	Michele	RESEARCH ON CHILDREN, YOUTH AND FAMILY - CHLA	Co-Investigator	HS GCP	no		
View	Law	Meng	NEURORADIOLOGY	Co-Investigator	HS GCP HIPAA	no		
View	Lee	Joshua	USC-Health Sciences (HSC)	Co-Investigator	HS HIPAA	no		
View	Neu	Scott	INSTITUTE FOR NEUROIMAGING AND INFORMATICS	Co-Investigator	HS HIPAA	no		
View	Toga	Arthur	INSTITUTE FOR NEUROIMAGING AND INFORMATICS	Co-Investigator	HS HIPAA	no		
View	Lane	Christianne	PREVENTIVE MEDICINE	Data Analyst/Statistician	HS GCP HIPAA	no	no	no
View	Mack	Wendy	BIOSTATISTICS	Data Analyst/Statistician	HS GCP HIPAA	no	no	no
View	David-DiMarino	Ernesto	Keck Medical Center of USC	Data Collector/Manager	HS HIPAA	no	no	yes
View	Erberich	Stephan	IMAGING SERVICES/RADIOLOGY - CHLA	Data Collector/Manager	HS GCP	no	no	yes
View	Jacobs	Ryan	Keck Medical Center of USC	Data Collector/Manager	HS	no	no	yes
View	Pant	Latika	INFORMATION TECHNOLOGY CLINICAL - CHLA	Data Collector/Manager	HS	no	no	yes
View	Pearlman	Laura	VITERBI SCHOOL OF ENGINEERING	Data Collector/Manager	HS HIPAA	no	no	yes

	Last Name	First Name	Organization	Study Role	Certifications	Obtain Consent	Interact with Participants	Access Identifiable Data
View	Sharma	Sumeet	INFORMATION TECHNOLOGY CLINICAL - CHLA	Data Collector/Manager	HS	no	no	yes
View	Sherazi	Hira	Clinical Translational Science Institute	Data Collector/Manager	HS HIPAA	no	no	yes
View	St.Clair	Patricia	SOL PRICE SCHOOL OF PUBLIC POLICY	Data Collector/Manager	HS HIPAA	no	no	no
View	Tran	Anhnhat	INFORMATION TECHNOLOGY CLINICAL - CHLA	Data Collector/Manager	HS	no	no	yes
View	Vacchani	Maulik	INFORMATION TECHNOLOGY CLINICAL - CHLA	Data Collector/Manager	HS	no	no	yes
View	Yi	Nancy	USC-CHLA IRB Information Technology	Data Collector/Manager	HS HIPAA	no	no	yes
View	Orechwa	Allison	NEUROSCIENCE	Research Assistant or Associate	HS	no		
View	Schmitz	Amanda	Clinical Translational Science Institute	Research Assistant or Associate	HS GCP HIPAA	no	no	yes
View	Chang	Todd	EMERGENCY MEDICINE - CHLA	Pilot investigator	HS GCP	no	no	no
View	Dhanireddy	Kiran	HEPATOBILIARY / PANCREAS AND LIVER TRANSPLANT SURGERY	Tester	HS GCP HIPAA	no	no	no
View	Doctor	Jason	CLINICAL PHARMACY	Tester	HS HIPAA	no	no	no
View	Haight	Cody	RESEARCH ON CHILDREN, YOUTH AND FAMILY - CHLA	Tester	HS	no	no	no
View	Hong	Kurt	GERIATRIC, HOSPITAL, PALLIATIVE, & GENERAL INTERNAL MEDICINE	Tester	HS GCP HIPAA	no	no	no
View	Idos	Gregory	GI AND LIVER DISEASES	Tester	HS GCP HIPAA	no	no	yes
View	Kim	Steve	UROLOGY - CHLA	Co-Investigator	HS GCP HIPAA	no	no	yes
View	Mody	Ameer	EMERGENCY MEDICINE - CHLA	Tester	HS GCP	no	no	yes
View	Wetzel	Randall	ACCM Research Oversight Committee - CHLA	Co-Investigator	HS GCP	no	no	yes

2.2. * **Is the Principal Investigator a student, resident, fellow, other trainee, or visiting scholar at USC/CHLA?**
○ Yes ◉ **No**

2.3. * **If there are any individual collaborators from other institutions, check here:** ☑

2.4. * **Does this study require Cancer Center Committee (CIC) approval?**
○ Yes ◉ **No**

2.4.1. * **Are Cancer Patients Involved?** ◉ **Yes** ○ No

2.5. * **Specify the group/organization who has reviewed this study for scientific merit:**

- ○ Federal Agency (e.g. FDA, NIH, CDC, DOE, NSF, DOJ, etc.)
- ○ USC Norris Clinical Investigations Committee
- ○ Doctoral Dissertation Committee
- ○ Other
- ○ None

2.5.1. * **Specify the other group/organization who has reviewed this study for scientific merit:**
SC-CTSI funded by NIH

2a. Collaborators from other institutions

This screen is required if there are collaborators from other institutions (Question 2.3.)

* **Collaborators from other institutions:**

	Last Name	First Name	Institution	Role	Engagement
View	ElMallah	Mohamed	Children's Hospital Los Angeles	Technical Lead for CHLA	

3. Required Department Approvals (for a study already submitted to the IRB)

This screen indicates the division/department approvals received once the proposal has been submitted.

3.1. * **Pending Division/Department Approvals:**
Name Division/Department Parent Campus
There are no items to display

3.2. * **Received Division/Department Approvals:**

Name	Division/Department	Parent Campus
INSTITUTE FOR NEUROIMAGING AND INFORMATICS	Department	USC-Health Sciences (HSC)
CLINICAL PHARMACY	Department	USC-Health Sciences (HSC)
NEURORADIOLOGY	Division	USC-Health Sciences (HSC)
RADIOLOGY	Department	USC-Health Sciences (HSC)
PREVENTIVE MEDICINE	Department	USC-Health Sciences (HSC)

3a.3. * **Other campus committees, services or departments that need to review and approve this protocol:**
Committee Name Committee Chair Approval Memo
There are no items to display

3a.4. * **Will the research be conducted through the CTU?**
○ Yes ◉ **No**

4. Funding Information

4.1. * **What existing, planned, or pending support will be used for this study?** (check all that apply)

- [ ] Cooperative Group (SWOG, COG, RTOG, etc.)
- [x] **CTSI**
- [ ] Department of Defense (DOD) Funds
- [ ] Departmental/Institutional Funds
- [ ] Federal Grant/Contract
- [ ] Foundation Grant/Contract
- [ ] Industry
- [ ] Intramural/Internal Grant
- [ ] Residual Funds
- [ ] State or Local Grant/Contract
- [ ] Subcontract from another institution
- [ ] No Funding
- [ ] Other

4.2. * **If the funding source has undergone separate review by the IRB (i.e., cooperative group grants, umbrella grants, multi-project/program grants, center grants), try to select it from the list using the "Add" button. If the funding source is not displayed in the list, enter the information in question 4.4.**

Grant #	Principal Investigator	Grant Title

There are no items to display

4.2.1. * **If the grants selected in question 4.2 fund multiple studies, please attach the specific pages of the grant that are relevant to THIS study.**

name	Version	Modified

There are no items to display

4.3. **If applicable, select a clinical trial from the TRUE2 system:**

4.4. * **Add the details of each source of funding for this study.**

	Sponsor	Principal Investigator	Type of Funding
View	NIH	Thomas Buchanan	Federal: Grant *

4.5. **To add a Related Award, please use the "Find Now" button below:**

* **Related Awards (uncheck checkbox to remove):**

ID	PI First Name	PI Last Name	Institutional Proposal Number	USC Award Number	Project Title	Prime Sponsor Name	Sponsor Name	Project Start Date	Co Investigators

There are no items to display

5. Type of Study Review

5.1. * **Select the type of review that you are requesting for this study:**

- ○ Full Committee Review
- ◉ **Expedited Review**
- ○ Exempt Review
- ○ Coded Specimens/Data

5.2. * **Attach the protocol here. For simple, investigator-initiated studies, a separate protocol may not be necessary. However, larger, complex, or multi-site studies require a fully developed protocol. If you have questions contact the IRB office to discuss.**

name Version Modified

There are no items to display

5.3. * **Attach the sponsor's template informed consent here.**

name Version Modified

There are no items to display

5.4. * **If any study documents are password protected, enter the passwords here.**

5.5. * **If there is a sponsor protocol number associated with this file, specify it here:**

5a. Type of Study Review - Expedited Review

This screen is required if you are requesting an expedited review for this study (Question 5.1.) If this is the incorrect review type, please return to page 5 to make changes.

5a. * **If you checked expedited review, please choose the applicable category from the list and attach your data collection forms below (click on the abbreviated category to receive the full description):**

	Short Description (click for full description)
☐	(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met...
☐	(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture...
☐	(3) Prospective collection of biological specimens for research purposes by noninvasive means...
☐	(4) Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves...
☑	**(5) Research involving materials that have been collected, or will be collected solely for nonresearch purposes...**
☐	(6) Collection of data from voice, video, digital, or image recordings made for research purposes.
☐	(7) Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies...

5a.1. * **Since you checked expedited review category 5, please attach a copy of the data collection forms, if applicable:**

name Version Modified

There are no items to display

6. Study Locations

6.1. * **Select each campus the study will be associated with (check all that apply):**

- ☑ **HSC - Health Sciences Associated Locations**

- [ ] UPC - University Park Associated Locations
- [x] **CHLA**

6.1.1. * **Will participants' informed consent be obtained at CHLA?**
○ Yes ◉ **No**

6.1.2. * **Will identifiable data or information about the research participants be obtained at CHLA or received by CHLA?**
◉ **Yes** ○ No

6.1.3. * **Will interaction or intervention with research participants occur at CHLA?**
○ Yes ◉ **No**

6.1.4. * **Will CHLA receive any direct federal support for this research?**
○ Yes ◉ **No**

You will have to submit a Ceded Review application to CHLA to conduct research at that site.

6.2. * **Will any research covered by this application be conducted at any other site not affiliated with USC or CHLA?**
○ Yes ◉ **No**

6a. HSC Location(s)

This screen is required if you indicated HSC - Health Sciences Associated Locations (Question 6.1.)

6a.1. * **Locations that recruitment, consent, and/or study procedures will be performed:** (check all that apply)

Location

- [ ] LAC+USC Medical Center
- [ ] LAC+USC Emergency Dept
- [ ] LAC+USC Outpatient Clinics
- [ ] LAC+USC 5P21 Building
- [ ] Keck Hospital of USC Facilities
- [ ] USC Norris Comprehensive Cancer Center Facilities
- [ ] Keck School of Medicine of USC
- [ ] USC Eye Institute
- [ ] USC Healthcare Consultation Center I or II
- [ ] USC Center for Health Professions (CHP)
- [ ] USC School of Dentistry
- [ ] El Monte Comprehensive Health Center *
- [ ] H. Claude Hudson Comprehensive Center *
- [ ] Roybal Comprehensive Health Center *
- [ ] Verdugo Hills Hospital
- [x] **Other location (e.g., subjects home, community)**

6a.2. * **Describe other location(s):**
Data will be extracted from the Cerner Electronic Health Record, physicially located in Kansas City but acessed over

the internet.

6a.3. * **If you are conducting this research in an LAC+USC location, specify the room numbers:**

6a.4. * **If you are conducting this research at a location marked with an asterisk "*", attach a letter of approval from the medical director.**

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There are no items to display

6c. CHLA Locations

This screen is required if your study is being conducted at CHLA

6c.1. * **CHLA Locations:**

- ☐ CHLA facilities
- ☐ AltaMed
- ☐ Other

9. Methods and Procedures - Selected Descriptors/Community Engaged Research

Note: The list of items below IS NOT an all-inclusive list of methods and procedures available to investigators. The list only includes items that will trigger additional questions specific to areas of research or are necessary for the review process.

9.1.

This study will involve: (check all that apply)

- * ☑ Prospective collection of data/specimens
- * ☑ Use of existing or retrospective data/specimens

9.2. **Study Procedures:** (check all that apply)

- ☐ Audio/Video Recordings or Photographs
- ☐ Behavioral Observations and/or Behavioral Experimentation
- ☐ Behavioral Interventions
- ☐ Deception
- ☐ Interview/Focus Groups
- ☐ Population-based Field Study
- ☐ Psychophysiological Testing
- ☐ Surveys/Questionnaires/Psychometric Testing
- ☐ Anatomic Pathology Specimens
- ☐ Approved/Investigational Devices
- ☐ Approved/Investigational Drugs and Biologics
- ☐ Biohazardous Substances (e.g. fresh tissue or tissue fluids, infectious agents, microorganisms, recombinant DNA, or shipment of biological material)
- ☐ Controlled Substances
- ☑ Creation of a Data or Tissue Repository

Creation of a repository is regulated by the IRB and you will be asked to provide information on the conditions under which the data or specimens may be accepted and shared, the collection protocol and informed consent, and the storage and management center operating procedures. If you have any

questions about this, please contact the IRB for guidance.

☐	Emergency Research (with exception from informed consent requirements)
☐	Gene Transfer Study
☐	Heritable Genetic Specimens or Germ Line
☐	Magnetic Resonance Imaging (MRI) or ultrasound other than clinically indicated
☐	Radiation Exposure Other Than Clinically Indicated Tests and/or Therapy (e.g. x-ray, CT, DEXA, radiation therapy, etc.)
☐	Stem Cell Research
☐	Substance Abuse Treatment (with medication)
☐	Venipuncture
☐	Other Medical Procedures/Considerations

9.5. * **Will data from this study be submitted to the NIH Genome-Wide Association Studies (GWAS) data repository?**
○ Yes ◉ **No**

9.6. * **Does your study involve community-engaged research (community-engaged research addresses community needs and involves the community in research plan, conduct of study, etc)?**
○ Yes ◉ **No**

10. Characteristics of the Study Subject Population

10.1. * **What is the maximum number of subjects you plan to recruit for this site? (Integer values only)**
1000000

10.1.2. * **If necessary, provide further explanation of accrual goals for all subject populations.**
This field requires a number, but "recruiting" is not part of our protocol. We will not be recruiting actively, instead we are creating a data warehouse that is refreshed regularly with data from EHRs of CHLA, Keck, and affiliated clinics.

10.2. * **Describe the inclusion criteria for enrollment. (HSC: *Refer to specific sections of the protocol/grant, if applicable*)**
Records present in Electronic Health Records

10.3. * **Describe the exclusion criteria for enrollment. (HSC: *Refer to specific sections of the protocol/grant, if applicable*)**
N/A

10.3.1. * **If there are any age, ethnic, language, or gender-based exclusion criteria, please provide justification.**
N/A

11. Research Objectives and Background

11.1. * **Describe the specific objectives or aims of the study and hypotheses or research questions. (HSC: *refer to specific sections of the protocol/grant, if applicable*)**
The objective of this study is to pilot the creation of a research data warehouse that investigators may use to conduct feasibility analysis and other studies using de-identified data.

11.2. * **Provide a summary of the background of the study, and explain how this research will contribute to existing knowledge. Describe previous work that provides a basis to show that the proposed research can be carried out without undue risk to human subjects. Include relevant citations. (HSC: *refer to specific sections of the protocol/grant, if applicable*)**
Creation of a research data warehouse is a standard practice of academic medical centers in order to create a secure, privacy protecting environment to manage clinical data. In this pilot we will use only data that meets HIPAA criteria for a limited data set.

12. Methods and Procedures - Prospective Studies

12.1. **Describe in detail the design and methodology of the study. Provide a detailed description of the planned data collection, specific outcomes, and criteria for evaluation and endpoint definition. If applicable, include information on stratification or randomization plans. Include the frequency and duration of each activity and the total length of subject participation. Identify and distinguish between those procedures that are standard of care and those that are experimental. (*Refer to specific sections of the protocol/grant, if applicable. Describe any differences between the protocol and the local site.*)***
Please see SOPs and extraction criteria in 15.2

12.2. * **Describe the statistical considerations for the study, how the sample size was determined, and how the results will be analyzed, if applicable. (*Refer to specific sections of the protocol/grant, if applicable*)**

13. Methods and Procedures - Retrospective Studies/Existing Data

This screen is required if you indicated the use of existing/retrospective data or specimens (Question 9.1.)

13.1. * **Do the retrospective/existing data involve records/specimens from deceased individuals?**
○ Yes ◉ **No**

15. Methods and Procedures - Creation of a Data or Tissue Repository

This screen is required if you selected Creation of a Data or Tissue Repository as a procedure (Question 9.2.)

A **Data or Tissue Repository** collects, stores, and distributes human specimens/data for research purposes (this is often referred to as ﷺbankingﷺ). Repository activities involve three components: (i) the collection of specimens/data; (ii) a storage and data management center for the repository; and (iii) the recipient investigators. A repository may also contain paper or computerized data.

If the research study is creating a repository of specimens/data that will be made available to other investigators outside of this research study (including other investigators at USC/CHLA), policies and procedures for operating the repository must be provided.

Operation of the repository and its data management center is subject to oversight by the IRB. The IRB will review the conditions under which specimens and data may be accepted and shared, ensuring adequate provisions to protect the privacy of subjects and maintain the confidentiality of data. The IRB will also review the specimens/data collection protocol and informed consent document(s) that would be used to collect specimens/data. It is often recommended that a Certificate of Confidentiality be obtained to protect the confidentiality of repository specimens and/or data.

As the above information explains, creation of a repository is not something that should be entered into lightly. If you have any questions as to whether the study will be or should be creating a repository, please contact the IRB for guidance.

15.1. * **Specify the organization/site at which the data/specimens will be banked.**
Health Sciences Campus Computing Center

15.2. * **Attach the Standard Operating Procedures and forms that will be used for the repository.**

name	Version	Modified
Data Specification | History	0.01	1/18/2015 6:17 PM
mini-DEWARS SOPs | History	0.02	4/2/2015 2:57 PM

22. Special Subject Populations

22.1. * **Indicate any vulnerable subject populations you intend or expect to enroll in the research:** (check all that apply)

- [ ] Normal Volunteers
- [ ] Employees or Students
- [ ] Adults not Competent to Consent (or likely to lose the capacity to consent during the study)
- [ ] Non-English Speaking Populations
- [ ] Minors (subjects under 18 years of age)
- [ ] Pregnant Women / Human Fetuses
- [ ] Neonates (infants under 30 days old)
- [ ] Prisoners/Detainees
- [ ] Wards
- [x] **None of the above**

23. Study Resources

23.1. * **Describe the time the investigators have available to conduct and complete the research and justify that it is sufficient. Please check-off the items that apply to this study.**

- [ ] Employed interns, residents, fellows, or postdocs with dedicated time to conduct this research.
- [x] **Employed faculty and or staff with dedicated time to conduct this research.**
- [ ] Students with dedicated time as part of their training to conduct this research.
- [ ] Volunteers
- [ ] Other

23.1.1. * **Please specify:**

23.2. * **Describe the staff and justify their qualifications. Please check-off the items that apply to this study.**

- [x] **All biomedical investigators are privileged and credentialed to perform the study activities in the study locations.**
- [x] **All study staff are trained and credentialed to perform the duties assigned to them.**
- [x] **All study staff have fulfilled the training mandated by their respective departments or institutions.**
- [ ] Other

23.2.1. * **Please specify:**

23.5 * **Describe the method(s) by which subjects will be identified, eligibility will be determined, and by whom.**
(deprecated field, used to be 23.1- only used for existing studies)
Research data warehouse will not include a selected sample.

24. Subject Recruitment and Informed Consent

24.1. * **Recruitment Tools that will be used by the local site (check a box only if your site will control the use or distribution of the recruitment tool):** (check ALL that apply)

- [ ] E-mail/Electronic Mailing List
- [ ] Brochure
- [ ] Flyers
- [ ] Letters
- [ ] Newspaper/Magazine Advertisements
- [ ] Radio/Television Announcements
- [ ] Subject or Participant Pool
- [ ] Telephone Scripts
- [ ] Verbal (Personal Solicitation)
- [ ] Website / Social Media Outlets
- [ ] Other
- [x] **None of the above**

24.3. Informed Consent and Waivers:

* **Check the type(s) of consent or waiver of consent planned for this study:** (check ALL that apply)

- [ ] Written/signed consent (participants will sign an informed consent document)
- [ ] An information sheet will be provided and/or verbal consent obtained
- [x] **Waiver of consent (participants will not be asked to sign a consent document or be given an information sheet)**
- [ ] Alteration of the elements of consent (participants will sign a consent document, but one or more of the basic required elements of consent will be altered or waived)

24.5. You indicated you are requesting a waiver of consent or a waiver/alteration of one or more elements of informed consent. The following questions are required:

24.5.1. The research involves no more than minimal risk to subjects and the waiver/alteration will not adversely affect the rights and welfare of the subjects because: (check ALL that apply and at least one answer from A at least one answer from B)

* **A. The study will:** (check all that apply)

- [x] **Only collect retrospective data or be performing secondary data analyses on existing data**
- [ ] Only collect information from observation of public behavior
- [ ] Only collect information from standard of care procedures
- [x] **Not contact participants**
- [ ] Not include any sensitive information that could be considered harmful if known (HIV status, drug/alcohol treatment records, etc.)
- [ ] Other

* **B. All Data/Information collected will:** (check ALL that apply)

- [ ] Not contain any identifiable information

- [x] **Be coded and the key codes kept separately and securely**
- [ ] Be kept in a locked/password protected area accessible only to study staff
- [ ] Other

24.5.2. * **Explain why the research could not practicably be carried out without the waiver or alteration:** (check ALL that apply)

- [x] **The data being collected are from existing records. Many of the subjects are lost to follow up, no longer seen at the hospital/facility, or deceased.**
- [x] **Participation in this study does not involve personal contact. The participants are not available to provide informed consent.**
- [x] **The study will be examining records from a large number of subjects. It is not feasible to attempt to contact all of them.**
- [ ] Other

24.5.3. * **Explain how, whenever appropriate, the subjects will be provided with additional pertinent information after participation:** (check ALL that apply)

- [x] **There is no foreseeable need to provide information to the subjects. If there is a need, the IRB will be contacted to discuss the specific situation.**
- [ ] The study is observational and any results generated from the study will not be applicable to the subjects or the care of the subjects.
- [ ] Other

**** Note: Waivers of consent are not applicable if the research is subject to FDA regulations, except when the following applies:**

- **Life-threatening situations, inability to communicate with or obtain legally effective consent from, the subject, insufficient time to obtain consent from the subject's legal representative and no alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life, even if research presents more than minimal risk [21CFR50.23];**
- **OR if the study satisfies the requirements under 21CFR50.24 Exception from Informed Consent Requirements for Emergency Research. Call the IRB office if you are planning to conduct this type of research as other regulatory requirements apply.**

25. Financial Obligation and Compensation

25.1. **Financial Obligation: Choose the response that best describes the cost to participants.** *

- ( ) All costs are covered by the sponsor or funder.
- ( ) Research costs are paid by the sponsor or funding agency; routine health care costs are the responsibility of the participants and/or their healthcare plans.
- ( ) All costs are the responsibility of the participants and/or their healthcare plans.
- ( ) Drug trials sponsored by the National Cancer Institute or other national institutes.
- (•) **There are no costs related to participation.**
- ( ) Other

25.1.A. * **Consent Text: The following financial obligation statement must be contained in the informed consents for this study:** (edit only as necessary. If your study has a contract, this language must be consistent with the contract language)
There is no cost to you for taking part in this study.

25.2. * **Payment for Participation: Describe how much, if any, financial or other form of compensation will be provided to the subject/family. Describe the requisite conditions that must be fulfilled to receive full or partial compensation. Describe the proposed method of timing and disbursement. If children are involved, please specifically address how the compensation will be distributed to children.**
N/A

25.3. **Research-Related Injury and Compensation for Injury: For studies of greater than minimal risk, if participants require care, medical services, or psychological services as a consequence of the research, who will provide this care? If applicable, describe who will pay for research-related injuries.**

* Medical and/or psychological care/treatment will be offered. In addition:

- ○ Costs for medical care from research-related injuries will be paid by the sponsor or funder.
- ○ Costs for medical care from research-related injuries will not be paid by the sponsor or funder.
- ○ Study has no sponsor or funder who accepts liability for injury.
- ○ Study funder provides the investigational drug or device, but only accepts liability when instructions followed.
- ○ Other

26. Participant Privacy and Data Confidentiality

26.1. **Privacy Protections:** Privacy is a participant's ability to control how other people see, touch, or obtain information about his/her self. Violations of privacy can involve circumstances such as being photographed or videotaped without consent, being asked personal questions in a public setting, being seen without clothing, being observed while conducting personal behavior, or disclosing information about abortions, HIV status, or illegal drug use.

* **Select the provisions to protect the privacy of the individual during screening, consenting, and conduct of the research:** (check ALL that apply)

- ☐ Research procedures will be conducted in person in a private setting.
- ☑ **Data will be captured and reviewed in a private setting.**
- ☐ Only authorized research study personnel will be present during research related activities.
- ☐ The collection of information about participants is limited to the amount necessary to achieve aims of the research.
- ☐ Participants will not be approached in a setting or location that may constitute an invasion of privacy or could potentially stigmatize them.
- ☐ Other (specify below)

26.2. **Confidentiality Precautions:** Confidentiality is an extension of the concept of privacy; it refers to the participant's understanding of, and agreement to, the ways identifiable information will be collected, stored, and shared. Identifiable information can be printed information, electronic information, or visual information such as photographs.

* **How will the research data/specimens be labeled?** (check ALL that apply)

- ☐ Data and/or specimens will be directly labeled with personal identifying information. (Identifiable)
- ☑ **Data and/or specimens will be labeled with a code that the research team can link to personal identifying information. (Coded)**
- ☐ Data and/or specimens will not be labeled with any personal identifying information, nor with a code that the research team can link to personal identifying information. (Anonymous)
- ☐ Other (explain below)

26.3. * **How will the research data and/or specimens be protected against inappropriate use or disclosure?** (check ALL that apply)

- ☐ Locked office

- ☐ Locked storage unit
- ☑ **Restricted access to authorized study personnel**
- ☑ **Secure computer/laptop**
- ☑ **Individual ID plus password protection**
- ☑ **Encryption of digital data**
- ☑ **Network Restrictions**
- ☑ **Security software (firewall, antivirus, anti-intrusion) is installed and regularly updated in all servers, workstations, laptops, and other devices used in the study**
- ☐ Restrictions on copying study related materials
- ☐ Destruction of source data immediately after data collection (to preserve anonymity of participants)
- ☐ Audio and/or video recordings will be transcribed and then will be destroyed
- ☐ Audio and/or video recordings will be modified to eliminate the possibility that study participants could be identified
- ☐ Photos or images will be modified to eliminate the possibility that study participants could be identified
- ☑ **Study personnel will sign statements agreeing to protect security and confidentiality of study information**
- ☑ **Access rights are terminated when authorized study personnel leave the study**
- ☐ Not Applicable
- ☐ Other (specify below)

26.4. * **Will coded or identified data and/or specimens be released to a third party (external to USC/CHLA)?**

○ Yes ◉ **No**

26.5. * **What will happen to the research data and/or specimens at the conclusion of the study?** (check ALL that apply)

- ☐ Direct identifiers and/or the key to the codes will be destroyed upon completion of the research (all data/specimens will be stripped of identifying information and/or the key to codes destroyed, paper documents shredded, electronic files purged, electronic media securely erased)
- ☑ **Retained for study record keeping purposes per institutional policy**
- ☐ Retained by the investigator for future research use
- ☐ Retained for future research use (create data or tissue repository/bank)
- ☐ Restricted use data will be destroyed or returned to the source
- ☐ No direct or indirect identifiers are being collected. The anonymous data and/or specimens will be retained at the discretion of the investigator
- ☐ This research is a clinical trial conducted under FDA regulations. Direct identifiers and/or the key to the codes will be destroyed as directed by the sponsor (IND/IDE holder) in accordance with FDA regulations
- ☐ The NIH requires that the records be retained for three years following the completion of the study
- ☐ Other (specify below)

26.6. * **Do you have, or plan to apply for, a DHHS issued Certificate of Confidentiality for this study?**

○ Yes ◉ **No**

27. Risk/Benefit Assessment - Risks

27.1. * **Risks, Discomforts and Potential Harms: Describe the risks associated with each research intervention. Include consideration of physical, psychological, social, and other factors.** (check all that apply)

- [ ] Discrimination based on genetic findings.
- [ ] Some people may find it upsetting to learn that they have certain mutations or errors in genes that could lead to future health problems for themselves or their children.
- [ ] Some of the questions may make the participant feel uneasy or embarrassed.
- [x] **There is a small risk that people who are not connected with this study will learn a participant's identity or their personal information.**
- [ ] The participants are providing highly sensitive, personal information in this study. If people not connected with the study learn this information, they could have problems getting a new job, keeping their current job, finding housing, or getting insurance (health, disability, or life insurance). In highly unlikely situations, they could be charged with a crime.
- [ ] Biomedical risks, including drug, device, biologics, radiation, surgery or other research procedures (please specify).
- [ ] The research includes the risk or disclosure that a participant may engage in self-harm or attempt suicide.
- [ ] Venipuncture risks including: mild discomfort (or pain), bruising and swelling around the puncture site, dizziness or fainting, or infection (rare).
- [ ] Other (specify below)

27.2. * **Describe the precautions that will be taken to minimize risks/harms.** (check all that apply)

- [ ] We will use our best efforts to keep the findings in this study as confidential as possible.
- [ ] Subjects can choose to skip or stop answering any questions that make them uncomfortable.
- [x] **Data will be coded and identity stored separate from data.**
- [ ] Data will be collected anonymously.
- [ ] Biomedical precautions, including precautions relating to drugs, devices, biologics, radiation, surgery or other research procedures (please specify).
- [ ] Venipuncture by individuals certified and privileged to perform the procedure.
- [ ] Other (specify below)

28. Risk/Benefit Analysis - Potential Benefits and Alternatives

28.1. * **Describe any potential for direct benefits to participants in the study:** (check all that apply)

- [ ] There are no direct benefits to research participants
- [ ] Improvement in some or all of participants' symptoms
- [ ] Improvement in some or all of participants' survival or longevity
- [ ] Information gained from testing or monitoring procedures
- [ ] Provision of drug or device
- [ ] Reduced side effects
- [ ] Other (explain below)
- [x] **There are no direct benefits to some or all of the research participants**

28.2. * **Describe potential benefits to society, if any.** (check all that apply)

- [x] **The advancement of knowledge**
- [ ] A new treatment or therapy for the condition under study
- [ ] None
- [ ] Other (explain below)

28.3. * **What are the alternatives to participation?** (check all that apply)

- [ ] Not participating

- ☐ Continue current medical care for their condition
- ☐ Participation in other research studies
- ☐ Palliative care
- ☐ No treatment or therapy
- ☐ Participate in other subject pool activities
- ☑ **Other (specify below)**

28.3.1 * **Describe other alternatives to participation:**
Subjects will not be consented. No alternative.

28.4. * **Risks in relation to benefits:**

- ☐ The potential benefits to the research participants justify exposure of the participants to the risks.
- ☑ **The potential benefits to humanity justify exposure of the participants to the risks.**
- ☐ Other (specify below)

35. Is the HIPAA Privacy Rule Applicable?

35.1. Do you intend to access, review, collect, use or disclose protected health information (PHI) in your research? Answer yes if you intend to do any of the following:

- Look at medical records (paper or electronic) to identify potential research participants
- Look at clinic logs to identify potential research participants
- Record demographic information obtained from medical records (paper or electronic)
- Record health information obtained from medical records (paper or electronic)
- Obtain information from laboratory reports, pathology reports, radiology reports or images, or other reports from medical or mental health testing and treatment
- Obtain information from medical billing records
- Record or use medical record numbers or other information that could be used to identify an individual (review the list of HIPAA identifiers below)
  - Name/Initials
  - Street address, city*, county*, precinct*, zip code*, or equivalent geocodes*
  - All elements of dates (except year) directly related to an individual (date of birth, admission date, discharge date, date of death)*
  - Elements of date, including year, for persons 90 or older
  - Telephone number
  - Fax number
  - Electronic mail address
  - Social Security Number
  - Medical record number
  - Health plan identification number
  - Account number
  - Certificate/license number
  - Vehicle identifiers and serial numbers, including license plate number
  - Device identifiers and serial number
  - Web addresses (URLs); Internet IP addresses
  - Biometric identifiers, including finger and voice print
  - Full face photographic images and any comparable images
  - Any other unique identifying number, characteristic, or code*

* ◉ **Yes** ○ No

35.2. * **Do you intend to record data that contains any of the 18 elements defined by HIPAA as identifiers (listed above), in your research?**
◉ **Yes** ○ No

35.3. * **Are you going to record only the personal identifiers marked with an asterisk (*)? If so, you may be able to obtain or use such health information from a healthcare provider for research purposes without an authorization. Under the HIPAA Privacy Rule, this data constitutes a limited data set. if you are creating or obtaining a limited data set, you must complete a Data Use Agreement. Attach a copy of the signed Data Use Agreement below.**

name	Version	Modified
Executed DUA CHLA | History	0.01	2/6/2015 6:32 AM
Executed DUA Keck | History	0.01	11/16/2014 8:11 AM

USC Template Data Use Agreement
** If your Data Use Agreement does not use USC's template form, please contact USC's Office of Compliance at complian@usc.edu or 213-740-8258 to submit the Data Use Agreement for further review and approval.

36. HIPAA Analysis

This screen is only required if you indicated HIPAA is applicable by answering "yes" to Question 35.1.

36.1. * **If you are using or accessing protected health information in order to identify potential participants, indicate if these activities fall under the rules for Activities Preparatory to Research, if you will be applying for a Partial Waiver of HIPAA Authorization for the purposes of screening and recruiting, or if neither option applies.**

- ○ (CHLA Only) Activities Preparatory to Research
- ◉ **Partial Waiver of HIPAA Authorization for screening, recruiting, and identifying participants**
- ○ None of the Above

36.2. * **If you are using or accessing protected health information to conduct the research, please select whether you will be obtaining authorization from the participant or requesting a Full Waiver of HIPAA Authorization.**

- ○ Obtaining HIPAA authorization from participant
- ◉ **Full Waiver of HIPAA Authorization**

36.2.1. * **If you are obtaining authorization from the participant, attach the HIPAA authorization forms here (USC Only). Please click here to download the HIPAA Authorization template forms from OPRS.**

name	Version	Modified
There are no items to display		

38. Partial Waiver of HIPAA Authorization

This screen is required only if HIPAA is applicable and you indicated you are requesting a Partial Waiver of HIPAA Authorization (Question 36.1.)

If you are applying for a partial waiver of authorization for the purposes of screening, recruitment, and subject identification, provide justification per 45 CFR 164.

38.1. * **How will you protect PHI (Protected Health Information) from improper use and disclosure?** (check all that apply)

- ☐ PHI will be used only for the purposes of assessing eligibility and identifying potential participants.
- ☑ **All source and research documents containing PHI will be stored and maintained in a locked/password protected area accessible only to study staff.**
- ☐ Study data will be coded or de-identified prior to being sent outside the study team.
- ☐ Other

38.2. * **How will you destroy identifiers at the earliest opportunity consistent with the conduct of the research?** (check all that apply)

- [ ] No identifiers or links to identifiers will be recorded during the data collection process.
- [ ] Direct or Coded Identifiers will be maintained only until the study is completed. After that, the identifiers will be shredded and electronic records purged.
- [ ] The link between study participants and study ID numbers will be destroyed (shredded/purged) when study activities are complete.
- [x] **Other**

38.2.1. * **Describe the plan to destroy identifiers at the earliest opportunity consistent with conduct of the research. If there is a health or research justification for retaining the identifiers, or if such retention is required by law, please explain.**
This is a data repository intended for archival use. The link between study identifiers and patients' medical records will be retained by the study staff in a separate repository accessed only on condition of specific IRB approvals and only limited to the population of patients described in the approved IRB protocol.

38.3. **By checking the "I Agree" box you are providing assurance that PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule.**

* [x] **I Agree**

38.4. * **The research could not practicably be conducted without the requested waiver or alteration because:** (check all that apply)

- [x] **PHI is required to identify potential participants who meet the eligibility criteria.**
- [ ] Other

38.5. * **The research could not practicably be conducted without access to and use of the PHI because:** (check all that apply)

- [x] **PHI is required to identify potential participants who meet the eligibility criteria.**
- [ ] During the recruitment process, PHI is needed in order to contact potential participants.
- [ ] Other

38.6. **By checking the "I Agree" box you are providing assurance that PHI requested will be the minimum amount necessary to conduct the research or meet the research objectives.**

* [x] **I Agree**

38b. Full Waiver of HIPAA Authorization

This screen is required only if HIPAA is applicable and you indicated you are requesting a Full Waiver of HIPAA Authorization (Question 36.2.)

If you are applying for a full waiver of authorization provide justification per 45 CFR 164.

38b.1. * **How will you protect PHI (Protected Health Information) from improper use and disclosure?** (check all that apply)

- [ ] No identifiers or links to identifiers will be recorded during the data collection process.
- [x] **All source and research documents containing PHI will be stored and maintained in a locked/password protected area accessible only to study staff.**
- [ ] Study data will be coded or de-identified prior to being sent outside the study team.
- [ ] Other

38b.2. * **How will you destroy identifiers at the earliest opportunity consistent with the conduct of the research?** (check all that apply)

- [ ] No identifiers or links to identifiers will be recorded during the data collection process.

- ☐ Direct or Coded Identifiers will be maintained only until the study is completed. After that, the identifiers will be shredded and electronic records purged.
- ☑ **The link between study participants and study ID numbers will be destroyed (shredded/purged) when study activities are complete.**
- ☐ Other

38b.3. **By checking the "I Agree" box you are providing assurance that PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule.**

* ☑ **I Agree**

38b.4. * **The research could not practicably be conducted without the requested waiver or alteration because:** (check all that apply)

- ☑ **It is not feasible to individually contact the large numbers of participants.**
- ☑ **It is not possible to locate many of the potential participants because they have left the area or are otherwise lost to follow up.**
- ☐ Other

38b.5. * **The research could not practicably be conducted without access to and use of the PHI because:** (check all that apply)

- ☑ **The data required for this study is only available in the PHI / medical records.**
- ☐ Other

38b.6. **By checking the "I Agree" box you are providing assurance that PHI requested will be the minimum amount necessary to conduct the research or meet the research objectives.**

* ☑ **I Agree**

39. Conflict Of Interest Information

39.1. Does the **Investigator**, **Research Personnel** or **Close Relation** have an ***ownership interest*** (any equity in a non-publicly traded company, regardless of value, or stock, stock options or warrants, in a publicly traded company of $5,000 or more excluding mutual funds) in:

- The sponsor of the research; or
- An entity that has a license or is negotiating a license to the intellectual property (e.g., patents) developed from this research; or
- An entity that has an economic interest in the research.

* ○ Yes ◉ **No**

39.2. Does the **Investigator**, **Research Personnel** or **Close Relation** have a ***management role*** (such as director, officer, scientific, or technical appointment), or any other role with significant decision-making authority, in:

- The sponsor of the research; or
- An entity that has a license or is negotiating a license to the intellectual property (e.g., patents) developed from this research; or
- An entity that has an economic interest in the research.

* ○ Yes ◉ **No**

39.3. Did the **Investigator**, **Research Personnel** or **Close Relation** receive in the last twelve months or does the Investigator, Research Personnel or Close Relation expect to receive in the next twelve months any payments for ***services*** (such as speakers fees, payments for consulting, participation on an advisory board, or assistance with protocol design) from:

- The sponsor of the research; or

- An entity that has a license or is negotiating a license to the intellectual property (e.g., patents) developed from this research; or
- An entity that has an economic interest in the research.

This does not include salary for services as an investigator/staff on the research study. Also excluded are payments from the federal government for services performed (i.e. peer review, study section participation, seminars, lectures, or service on advisory committees).

* ○ Yes ◉ **No**

39.4. Does the **Investigator**, **Research Personnel** or **Close Relation** personally receive **intellectual property rights** (e.g. patents, copyrights, or royalties) directy from:

- The sponsor of the research; or
- An entity that has a license or is negotiating a license to the intellectual property (e.g., patents) developed from this research; or
- An entity that has an economic interest in the research.

This does not include royalties paid directly from USC

* ○ Yes ◉ **No**

40. Additional Supporting Documents

40.1. * **Attach any other documents that have not been specifically requested in previous questions, but are needed for IRB review.**

name	Version	Modified
Joshua Lee HIPAA Training Certificate | History	0.01	1/23/2015 5:03 PM
Update on IRB for DEWARS Pilot - Daniella Meeker.pdf | History	0.01	11/16/2014 8:53 AM

40.2. * **If there is any additional information that you wish to communicate about the study include it below. Please note, this section should not be used instead of the standard application items.**

Per discussion with Drs. Spicer and Rose:

(1) Prior to submitting a request, end users will agree to terms of service, including attestation that they will not attempt to re-identify individuals in the de-identified data sets they receive.

(2) End users attesting to these terms will NOT be required to seek additional IRB approval to receive de-identified data.

(3) End users seeking to use these data to re-identify patients for recruiting will be required to seek separate IRB approval.

(4) This project will not involve any re-identification or patient contact.

99. Instructions for Submission

You have reached the end of the application. When you are sure of the content, the following steps may be taken to submit your application for review.

1. Click the **"Finish"** button on the top or bottom application navigator bar to return to the workspace.
2. Use the **Hide/Show Errors** above to determine that all sections of the application are filled out correctly.
3. Use the **"Send Study Ready Notification"** activity to send an email to the Principal Investigator and Co-Investigators with instructions for reviewing and submitting the application.
4. **All listed Co-Investigators (indicated in item 2.1.) must use the "Agree to Participate" activity and answer yes.**

5. Once all the Co-Investigators have agreed to participate, the **Principal Investigator** (indicated in item 2.1.) can submit the application by using the **"Submit Application to____"**, where ____ indicates the IRB you are submitting to.
6. The PI will have to check the PI endorsement box. The PI will also have to check the student endorsement box if it is applicable.
7. The application is submitted. The state indicator in the top left of the workspace will no longer display Pre Submission.
8. The PI and Study Contact Person will receive an email confirming the application has been submitted.

2a. Collaborator from Other Institution

2a.1. * **First Name:**
Mohamed

2a.2. * **Last Name:**
ElMallah

2a.3. * **Institution:**
Children's Hospital Los Angeles

2a.4. * **Role:**
Technical Lead for CHLA

2a.5. * **Will participants' informed consent be obtained by this person?**
○ Yes ○ No

2a.6. * **Will identifiable data or information about the research participants solely for the purposes of the research project be obtained by this person?**
○ Yes ○ No

2a.7. * **Will this person interact or intervene with research participants?**
○ Yes ○ No

2a.8. * **Will the institution named in 2a.3. receive any direct federal support for this research?**
○ Yes ○ No

2a.9. * **Will any research activities occur at the Institution named in 2a.3.?**
○ Yes ○ No

2a.10. **Documents:**
name Version Modified
There are no items to display

4.4. Funding Source

Please enter the fields below and click 'OK' when done.

4.4.1. * **Name of Sponsor:**
NIH

4.4.2. * **Named Principal Investigator:**
Thomas Buchanan

4.4.3. Institution awarded the grant-award:
SC-CTSI

4.4.4. Grant-award number provided by the Sponsor:
UL1TR000130

4.4.5. Title of the Funding Project, if applicable:

4.4.6. * Type of Funding:
Federal: Grant *

4.4.7. Attach a copy of the proposal/contract/grant with the project budget. (salary information need not be displayed or included.)

name	Version	Modified

There are no items to display