



Proposal #HS-15-00409

University of Southern California Health Sciences Campus  
 Institutional Review Board  
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Date: Aug 03, 2015, 02:33pm  
 To: [Elizabeth Benjamin](#)  
 TRAUMA AND CRITICAL CARE

From: Health Sciences Institutional Review Board  
 General Hospital, Suite 4700  
 1200 North State Street  
 Los Angeles, CA 90033  
 (323) 223-2340

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**TITLE OF PROPOSAL:**

Continuity versus Discontinuity for Bowel Injury in Damage Control Laparotomy: A Prospective Multi-Institutional Study ([Continuity vs Discontinuity in Damage Control Laparotomy](#))

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Action Date: **8/3/2015**

Action Taken: **Approve**

Committee: Institutional Review Board Chairman

Note: Your iStar application and attachments were reviewed by the expedited mechanism by Dr Darcy Spicer on August 3, 2015.

The project was APPROVED.

Approval of your study will expire at the end of the day (midnight) on August 2, 2016.

The materials submitted and considered for review of this project included:

1. iStar Application, dated 07/28/15
2. Protocol, dated 06/19/15
3. Data Collection Form
4. Letter of Support (Joseph DuBose), dated 07/06/15

This study was submitted for expedited review according to 45 CFR 46.110(b) (5).

The IRB finds that no greater than minimal risk to children is presented (45 CFR 46.404).

The research protocol is designed for conditions or for a subject population for which assent and parental or guardian permission is not a reasonable requirement to protect the subjects. An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and the waiver is not inconsistent with Federal, State, or local law.

In approving this research the IRB determined that all of the following were satisfied: (1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, only those risks and benefits that may result from the research are considered (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). (3) Selection of subjects is equitable (the purposes of the research and the setting in which the research will be conducted were taken into account). (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative. (5) Informed consent will be appropriately documented. (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

As the Principal Investigator you are required to ensure that this research and the actions of all project personnel involved in conducting the study will conform with the research project and its modifications approved by the IRB, IRB Policies and Procedures, and applicable state laws. Failure to comply may result in suspension or termination of your research project, notification of appropriate governmental agencies by the IRB, and/or suspension of your freedom to present or publish results. Any proposed changes in the research project must be submitted, reviewed and approved by the IRB before the change can be implemented. The only exception is a change necessary to eliminate apparent immediate hazards to the research subjects. In such a case, the IRB should be promptly informed of the change following its implementation for IRB review. You must inform the IRB immediately if you become aware of any violations of applicable state laws or IRB Policies and Procedures for the protection of human subjects. You are required to notify the IRB office in the event of any action by the sponsor, funding agency or FDA, including

warnings, suspension or termination of your participation in this trial. You must maintain all required research records and recognize the IRB is authorized to inspect these records.

IRB approval is valid for a maximum period of one year with continuing review by the IRB required at least every year in order to maintain approval status. You may not enter subjects on the study before IRB approval or if IRB approval expires. In the latter case you must immediately contact the IRB to obtain permission to continue subjects on the trial. You must submit a Continuing Review Form sufficiently (one to two months) prior to your study expiration date to permit IRB review before the expiration date.

You must inform the IRB of any unanticipated adverse event or injury no later than ten (10) business days following the time it becomes known that a subject suffered an adverse event/injury. To report external or internal adverse events to the IRB, you must complete and submit the Reportable Event forms in iStar. Furthermore, you must inform the IRB immediately of any significant negative change in the risk/benefit relationship of the research as originally presented in the protocol and approved by the IRB.

#### INFORMED CONSENT

The request for a WAIVER OF INFORMED CONSENT is approved as iStar item 24 adequately documents that: (a) the research involves no more than minimal risk to the subjects; (b) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (c) the research could not practicably be carried out without the waiver or alteration; and (d) the subjects will be provided with additional pertinent information after participation (where appropriate).

#### HIPAA AUTHORIZATION

The request for a waiver of HIPAA Authorization is approved. The investigator has provided justification by specifically documenting the following: (1) The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements: (a) There is an adequate plan to protect the identifiers from improper use and disclosure; (b) There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and (c) There are adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart. (2) The research could not practicably be conducted without the waiver or alteration; and (3) The research could not practicably be conducted without access to and use of the protected health information.

You must use the data collection form submitted.

Version: 1.2

Application Version Date: 7/28/2015

Date: Monday, August 03, 2015 2:34:11 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

Continuity versus Discontinuity for Bowel Injury in Damage Control Laparotomy:  
A Prospective Multi-Institutional Study

### 1.3. \* Short Title

Continuity vs Discontinuity in Damage Control Laparotomy

### 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.

Introduction: Damage control surgery is the standard of care in the unstable trauma patient with hollow viscus injury. Optimal management of the hollow viscus injury, specifically with discontinuity, anastomosis, or diversion, however, remains controversial. Although several potential risk factors for anastomotic dehiscence have been identified, there are no prospective studies investigating the outcomes of patients managed with bowel discontinuity versus anastomosis during damage control laparotomy.

Study Design: Prospective, Multi-Institutional Study

Aim: To determine the physiologic consequence of bowel discontinuity after damage control laparotomy. To determine the differences in anastomotic dehiscence, abdominal sepsis, and ischemia after damage control laparotomy with bowel discontinuity versus immediate reconstruction.

Methods: All patients undergoing damage control laparotomy for trauma with concurrent hollow viscus injury will be eligible for the study. Demographic, physiologic, operative, and post-operative data will be collected including transfusion and resuscitative fluids, vasopressors, pre and operative time, overall injury burden and operative interventions. The study population will be stratified based on management of the bowel on initial operation (discontinuity vs. continuity) with a secondary stratification based on final bowel management (primary anastomosis vs. end ostomy vs. anastomosis with protective ostomy). Bivariable and multivariable analyses will be performed to determine differences in bowel ischemia, anastomotic dehiscence, abdominal sepsis, and mortality as well as to identify independent risk factors for outcome variables.

### 1.5. \* Select which IRB you are requesting review from:

USC-Health Sciences (HSC)

## 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
<a href="#">View</a> Benjamin	Elizabeth				no	no	yes

Last Name	First Name	Organization	Study Role	Certifications	Obtain Consent	Interact with Participants	Access Identifiable Data
		TRAUMA AND CRITICAL CARE	Principal Investigator	HS GCP HIPAA			
<a href="#">View</a>	Demetriades Demetrios	TRAUMA AND CRITICAL CARE	Co-Investigator	HS GCP HIPAA	no	no	yes
<a href="#">View</a>	Wong Monica	TRAUMA AND CRITICAL CARE	Research Coordinator	HS GCP HIPAA	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

## 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
<a href="#">View</a>	DuBose Joseph	University of Maryland Medical Center	Co-Principal Investigator	<b>Institution May be Engaged</b>

## 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
SURGERY	Department	USC-Health Sciences (HSC)
TRAUMA AND CRITICAL CARE	Division	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.)
- 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

## 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  
[AAST Multicenter Bowel Study](#) | [History](#) 0.01 6/28/2015 2:49 PM

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

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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
<a href="#">AAST data collection variables.docx</a>   <a href="#">History</a>	0.01	6/29/2015 12:13 AM

## 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
- CHLA

6.2. \* Will any research covered by this application be conducted at any other site not affiliated with USC or CHLA?

Yes  No

6.2.1. \* Is USC/CHLA the coordinating center (i.e. the site having primary responsibility for the overall conduct of the study)?

Yes  No

6.2.2. \* Will any of the research activities covered by this application be conducted at the other sites?

Yes  No

**(\*\*Please note that this question has been deprecated in the iStar system. Please make the appropriate selections above in Section 6.1., 6.2. and 6.3.)**

**\* (old 7.1.1.) Multi-Site Information Management Plan:**

As sites are added, the current IRB will be amended.

This study will be conducted through the American Association for the Surgery of Trauma (AAST)

Multicenter Trials group. There is a secure, password protected, deidentified data collection tool generated through the AAST for centralized data collection.

All other communication will be via email.

### 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
  - Other location (e.g., subjects home, community)

**6a.2. \* Describe other location(s):**

**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.**

name Version Modified  
There are no items to display

### 6d. Other Sites/Institutions

*This screen is required if you indicated that USC/CHLA is the coordinating site or is conducting the study at other sites (Question 6.3.).*

**6d.1. List ALL participating sites below:**

Site Name	Address	Engagement
<a href="#">View</a> University of Maryland Medical Center	22 South Greene Street, Baltimore, MD 21201	

**6d.3.**



**\* Describe how information and communication between the sites will be managed (including reportable events, study amendments, etc.).**

As sites are added, the current IRB will be amended.

This study will be conducted through the American Association for the Surgery of Trauma (AAST) Multicenter Trials group. There is a secure, password protected, deidentified data collection tool generated through the AAST for centralized data collection.

All other communication will be via email.

## 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
- 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

**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)  
400

- 10.1.1. \* If this is a multi-site study, indicate the projected total subject accrual. (Integer values only)  
800

- 10.1.2. \* If necessary, provide further explanation of accrual goals for all subject populations.  
We plan to close enrollment after one year of open enrollment. Projected (local) totals are based on our site's registry data.

- 10.2. \* Describe the inclusion criteria for enrollment. (HSC: Refer to specific sections of the protocol/grant, if applicable)  
Please refer to Patient Selection (page 5) in the protocol.

- 10.3. \* Describe the exclusion criteria for enrollment. (HSC: Refer to specific sections of the protocol/grant, if applicable)  
Please refer to Patient Selection (page 5) in the protocol.

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

## 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)  
Please refer to the "rational" and "description" section of the protocol

- 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)  
Please refer to the "background and significance" section of the protocol

## 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 refer to Methods (page 2) and Description (page 5) of the protocol. In summary, all participating sites will screen for patients and collect study variables on eligible patients, as per protocol. Data collected will be coded. Coded data will be entered into the study's online Data Collection Tool (maintained by the AAST multicenter study site).

At our local site, patients will be identified during the daily pass-on meetings held in the conference room between the trauma teams. Eligible patients will have their charts reviewed for data abstraction.

The co-investigators will perform data analysis using the coded data obtained from the Data Collection Tool.

**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)**

Please refer to Methods (Page 2) of the protocol. This is a descriptive study. Sample size was determined by our site's registry data. We plan to enroll for a period of one year only.

## 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
- None of the above

### 22e. Special Subject Populations - Minors

*This screen is required if you indicated Minors (subjects under 18 years of age) as a special subject population (Question 22.1.)*

**22e.1. \* Provide a justification for involving minors in this research: (check all that apply)**

- The condition, situation, or issue under study affects minors.**
- Adults have already been studied, but we do not yet know how minors are affected.
- The condition does not affect adults, only children.
- Other

**22e.2. \* Choose the proposed category of permissible research with children.**

Category

- a. 46.404 - Research not involving greater than minimal risk.**
- b. 46.405 - Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
- c. 46.406 - Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- d. 46.407 - Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

Category

- 22e.3. \* Indicate the age ranges of the minors involved in this research: (check all that apply)
- 14 years - 17 years

## 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.
- 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.

- All biomedical investigators are privileged and credentialed to perform the study activities in the study locations.**
- All study staff are trained and credentialed to perform the duties assigned to them.**
- 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)  
Subjects will be identified at daily service pass on rounds held in the conference room.

## 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
- None of the above**

**24.3. Informed Consent and Waivers:**

**\*\* Please note that child assent and parental permission will be addressed on subsequent pages. Do not complete the following consent questions if adults will not be participating in the study. \*\***

**\* 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
- 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)**

- 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**
- 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
- 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)**

- 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.**
- Participation in this study does not involve personal contact. The participants are not available to provide informed consent.**
- 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)**

- 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.**

## 24A. Assent

### 24A.1. Assent and Waivers:

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

- Written assent (participants will sign an assent document)
- An information sheet will be provided and/or verbal assent obtained
- Waiver of assent (participants will not be asked to sign an assent document or be given an information sheet)**

### 24A.3. Assent Waiver:

**\* Indicate the applicable justification(s) for a waiver of assent:**

- The age, maturity, or psychological state of children to be enrolled make them incapable of providing assent.
- The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is only available in the current context of the research.
- The research involves no more than minimal risk to children; the waiver would not adversely affect the rights and welfare of the children; the research could not practicably be carried out without the waiver; and, if appropriate, participants will be provided with pertinent information after participation.**

**In order to qualify for a waiver of assent where the research is no more than minimal risk (the third option above), the following questions are required:**

**24A.3.1. The research involves no more than minimal risk to subjects and the waiver will not adversely affect the rights and welfare of the subjects because:** (check ALL that apply and at least one answer from A and B)

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

- 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**
- 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

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

**24A.3.2. \* Explain why the research could not practicably be carried out without the waiver or alteration: (check all that apply)**

- 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.
- Participation in this study does not involve personal contact. The participants are not available to provide informed consent.
- The study will be examining records from a large number of subjects. It is not feasible to attempt to contact all of them.
- Other

**24A.3.3. \* Explain how, whenever appropriate, the subjects will be provided with additional pertinent information after participation: (check all that apply)**

- 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

## 24P. Parental Permission

### 24P.1. Parental Permission and Waivers:

**\* Check the type(s) of parental permission or waiver of permission planned for this study: (check all that apply)**

- Written permission (parents or legal guardians will sign a consent document)
- An information sheet will be provided and/or verbal permission obtained
- Waiver of permission (parents or legal guardians will not be asked to sign a consent document or be given an information sheet)
- Alteration of the elements of permission (parents or legal guardians will sign a consent document, but one or more of the basic required elements of consent will be altered or waived)

### 24P.3. Parental Permission Waiver:

**\* Check the applicable justification for a waiver of parental permission:**

- The research involves no more than minimal risk to children; the waiver would not adversely affect the rights and welfare of the children; the research could not practicably be carried out without the waiver; and, if appropriate, participants will be provided with pertinent information after participation.
- Parental permission is not a reasonable requirement to protect the participants in the study (e.g., neglected, abused, or homeless children) and research involves no more than minimal risk to children; the waiver would not adversely affect the rights and welfare of the children; the research could not practicably be carried out without the waiver; and, if appropriate, participants will be provided with pertinent information after participation.

**You indicated you are requesting a waiver permission or alteration of one or more elements of parental permission. The following questions are required:**

**24P.3.1. 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 and B)**

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

- 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**
- Not contact participants**
- Not include any sensitive information that could be considered harmful if known (HIV status, drug/alcohol treatment records, etc.)**
- Other

**\* B. Data/Information collected will:** (check all that apply)

- Not contain any identifiable information
- Be coded and the key codes kept separately and securely**
- Be kept in a locked/password protected area accessible only to study staff**
- Other

**24P.3.2. \* Explain why the research could not practicably be carried out without the waiver or alteration:** (check all that apply)

- 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.**
- Participation in this study does not involve personal contact. The participants are not available to provide informed consent.**
- The study will be examining records from a large number of subjects. It is not feasible to attempt to contact all of them.
- Other

**24P.3.3. \* Explain how, whenever appropriate, the subjects will be provided with additional pertinent information after participation:** (check all that apply)

- 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

## 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.**  
There is no payment for participation.

**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

**26.4.1. \* Specify what data and/or specimens will be released, to whom (the individuals and/or agencies), and why.**

Coded data will be entered onto the study's online Data Collection Tool. When enrollment is finished all coded data will be released to the Co-Investigators (2 USC co-I, and 1 external co-I) for analysis.

**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.
- 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.
- 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)

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

- 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:**

Not applicable. The treatments being observed are the current standards of care.

**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)

\*  **Yes**  No

**35.2. \* Do you intend to record data that contains any of the 18 elements defined by HIPAA as identifiers (listed below), in your research?**

**Yes**  No

- 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\*

**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
There are no items to display		

[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 [complan@usc.edu](mailto:complan@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.**
- Other

**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.**

\*  **I Agree**

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

- 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)**

- 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.**

\*  **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.
- 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) directly 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

**39.5.** **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

## 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  
There are no items to display

**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.**

## 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:**

Joseph

**2a.2. \* Last Name:**

DuBose

**2a.3. \* Institution:**

University of Maryland Medical Center

**2a.4. \* Role:**

Co-Principal Investigator

**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

## 6d.1 Other Site

Please complete the form below and click 'OK' when done.

**6d.1.1. \* Site Name:**

University of Maryland Medical Center

**6d.1.2. \* Address:**

22 South Greene Street, Baltimore, MD 21201

**6d.1.3. \* Briefly describe the activities that will occur at this site:**

Dr. Dubose is the co-investigator of this study. His activities include:  
Study design, data analysis of coded data, manuscript writing.

His site will also participate in the study once our site and his site obtain IRB approvals:  
screening patients  
collecting data  
entering coded data in AAST's Data Collection Tool.

**6d.1.4. Non-USC/CHLA Individuals' activities at the site:****\* 6d.1.4.1.**

**Recruitment and Consent:**

Inform potential participants of the availability of the research, provide study contact information, or seek permission for investigators to contact the potential participants?

Yes  No

Obtain informed consent from the research participants?

Yes  No

\* **6d.1.4.2. Participant Data and Information:**

Release to the study investigators data or information about the research participants that have been collected for non-research purposes?

Yes  No

Obtain identifiable data or information about the research participants solely for the purposes of the research project?

Yes  No

\* **6d.1.4.3. Patient Contact and Intervention:**

Interact with the research participants for routine care, follow up or commercial services?

Yes  No

Interact or intervene with research participants for research purposes (including performing procedures or manipulating the environment)?

Yes  No

\* **6d.1.5. Will this site receive any direct federal support for this research?**

Yes  No

**Your answers indicate that the other institution is engaged in the research. You must answer the following:**

**6d.1.6. Does the institution have an IRB?**

Yes  No

**6d.1.6.1. Attach the IRB approval or, if the site has elected to have USC/CHLA be the IRB of record, attach the IRB authorization agreement.**

**6d.1.6.2. Please attach a letter of agreement for the conduct of the study from that site. *The IRB will contact that individual to verify authority, and to obtain an IRB authorization agreement from that site. The IRB authorization agreement will define reporting between the study site, the investigators and the IRB.***

**6d.1.7. Please provide the following assurance:**

All unexpected problems, protocol modifications, and interim results will be communicated to the other sites and regulatory agencies (as applicable).

**6d.1.8. Please attach a letter from the site acknowledging that the study may be conducted there.**

name

Version Modified

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**6d.1.9. Will any of the personnel at this institution carry out research activities such as obtaining consent or conducting study procedures?** (Deprecated Field - used to be 6c.1.3. - only used for old studies)

Yes  No

**6d.1.10. If yes, indicate under which category(ies) the institution is engaged (see guidance) and attach a copy of the IRB approval from that site below.** (Deprecated Field - old 6c.1.4. - only used for old studies)

**Short Description**

- 
- (1) Institutions that receive an award through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human subjects research.
- 
- (2) Institutions whose employees or agents intervene for research purposes with any human subjects of the research by performing invasive or noninvasive procedures.
- 
- (3) Institutions whose employees or agents intervene for research purposes with any human subject of the research by manipulating the environment.
- 
- (4) Institutions whose employees or agents interact for research purposes with any human subject of the research.
- 
- (5) Institutions whose employees or agents obtain the informed consent of human subjects for the research.
- 
- (6) Institutions whose employees or agents obtain for research purposes identifiable private information or identifiable biological specimens from any source for the research.

WAIVER OF HIPAA AUTHORIZATION APPLICABLE FOR RECRUITMENT:  
The request for a waiver of authorization is approved solely for the purposes of obtaining protected health information to screen and/or recruit potential research subjects into the study. Please note that you may be asked to provide a copy of this waiver to obtain or access to this protected health information. PLEASE NOTE: YOU MAY LOOK AT, BUT NOT RECORD HIV TEST RESULTS.

Attachments:

Approved Documents: [view](#)

This is an auto-generated email. Please do not respond directly to this message using the "reply" address. A response sent in this manner cannot be answered. If you have further questions, please contact your IRB Administrator or IRB/CCI office.

The contents of this email are confidential and intended for the specified recipients only. If you have received this email in error, please notify [istar@usc.edu](mailto:istar@usc.edu) and delete this message.