Date: Wednesday, December 15, 2021 8:24:08 AM

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ID: IRB#17-000048 View: NEW 1.1 - Study Title and Key Personnel

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Preoperative Alpha Blockade for Pheochromocytoma

NCT03176693

Document Date: June 15, 2021

Study Title and Key Personnel

All items marked with a red asterisk (*) are required. Items without an asterisk may or may not be required depending on whether the items are applicable to this study.

1.0 ***Full Title of the Submission:**
Randomized Controlled Trial of Preoperative Alpha Blockade for Pheochromocytoma

1.1 **Protocol Version Date and/or Number:**
v1

2.0 ***Working or Lay Title:**
Randomized Controlled Trial of Preoperative Alpha Blockade for Pheochromocytoma

3.0 **Principal Investigator:**

3.1 ***Name:** MICHAEL YEH
Degree(s): If degrees are not shown here, please add them to the next section, Section 1.1a/Item 1.0, which will then update the Principal Investigator's webIRB account information.
M.D.

3.2 **UCLA Title:**

3.3 ***Will the Principal Investigator conduct the informed consent process with potential study participants?**

- (●) **Yes**
- ( ) No
- ( ) Not Applicable

3.4 ***Is the Principal Investigator an undergraduate student, graduate student, post-doctoral fellow, or resident physician?**

( ) Yes (●) **No**

3.4.1 **If you answered "yes" to the above question, indicate the Faculty Sponsor for this study.**

3.5 **UCLA Policy 900 defines types of UCLA employees who may be eligible to serve as a Principal Investigator. Check the policy to see if the Principal Investigator for this study needs an exception to the eligibility requirements.**

If an exception is needed, either attach the letter of exception here, or indicate a Faculty Sponsor in the above item.

Document Name	Document Version #
There are no items to display	

4.0 **Study Contact Person: Indicate the person, in addition to the Principal Investigator, who should receive all of the study correspondence.**
MASHA LIVHITS

5.0 **List the key personnel and study staff below.**

Note: All personnel listed below are required to complete CITI training courses (except for Fund Managers and Regulatory Coordinators). Please verify CITI training completion for all personnel prior to submitting a New Study application or Amendment application to add personnel. Verify using the Training Log tab in the application workspace (accessible by clicking the Exit button at the bottom of this page). HIPAA training is also required if personnel will be accessing protected health information.
Please make sure to have all personnel update their webIRB profile and contact information.
Instructions on how to update the webIRB profile are available here.

Name	Department	Role	Other Role (if applicable)	Will Obtain Consent?	Manage device accountability?	Access to personally identifiable info?	Access to code key?

View	YASMINE ASSADIPOUR	SURGERY-GENERAL	Co-Investigator	yes	Not Applicable	Yes	Yes
View	JOE HONG, MD	ANESTHESIOLOGY & PERIOPERATIVE MEDICINE	Co-Investigator	yes	Not Applicable	Yes	Yes
View	Ming-Yeah Hu	DEANS OFFICE-SCHOOL OF MEDICINE	Research Assistant	no	Not Applicable	Yes	Yes
View	NIRAV KAMDAR	ANESTHESIOLOGY & PERIOPERATIVE MEDICINE	Co-Investigator	yes	Not Applicable	Yes	Yes
View	ERIC KUO	SURGERY-CHAIRMAN	Co-Investigator Research Assistant Statistician or Data Analyst Study Coordinator Data Manager	yes	Not Applicable	Yes	Yes
View	JASON LEE	ANESTHESIOLOGY & PERIOPERATIVE MEDICINE	Co-Investigator	no	Not Applicable	Yes	Yes
View	JUSTIN LEE	DEANS OFFICE-SCHOOL OF MEDICINE	Research Assistant	no	No	Yes	Yes
View	MASHA LIVHITS	SURGERY-GENERAL	Co-Principal Investigator	yes	Not Applicable	Yes	Yes
View	MELISSA MENDOZA	SURGERY-GENERAL	Study Coordinator	no	Not Applicable	Yes	Yes
View	Dalena Nguyen	SURGERY-GENERAL	Study Coordinator	no	Not Applicable	Yes	Yes
View	Joana Ochoa	SURGERY-GENERAL	Research Assistant	yes	Not Applicable	Yes	Yes
View	CLARISSA RO	SURGERY-GENERAL	Study Coordinator	no	Not Applicable	Yes	Yes
View	MAX SCHUMM	SURGERY-CHAIRMAN	Research Assistant	yes	Not Applicable	Yes	Yes
View	CHI-HONG TSENG	MEDICINE-GENERAL MEDICINE & HLTH SRVCS.	Statistician or Data Analyst	no	No	Yes	Yes
View	RUN YU	MEDICINE-ENDOCRINOLOGY	Co-Investigator	yes	Not Applicable	Yes	Yes
View	KYLE ZANOCCO	SURGERY-GENERAL	Co-Investigator	yes	Not Applicable	Yes	Yes
View	CATHERINE ZHU	SURGERY-CHAIRMAN	Research Assistant	yes	Not Applicable	Yes	Yes

ID: IRB#17-000048 View: NEW 1.1a - Other Personnel

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Other Personnel

All items marked with a red asterisk (*) are required. Items without an asterisk may or may not be required depending on whether the items are applicable to this study.

1.0 Principal Investigator

1.1 **Name:** MICHAEL YEH
***Please type the Degree(s):** M.D.

1.2 **Principal Investigator's UCLA Department:** SURGERY-CHAIRMAN

1.3 ***Protocol's UCLA Home Department:** SURGERY-CHAIRMAN

This response defaults to the PI's payroll department. If you wish to affiliate this protocol with another department, please select the department from the list above.

For tips on effective search, please see guidance to the right.

2.0 If there will be other types of personnel working directly under the PI's supervision on aspects of the study, provide their name, title and institution, indicate their responsibilities, training and qualifications and complete Item 2.1.

Please also indicate, if applicable, whether that person will obtain consent, manage device accountability, have access to personally identifiable information and/or have access to the code key.

Please use a new entry to add each individual unless describing a class of individuals who rotate through the study team (see guidance area to the right).

Note: If there will not be other types of personnel go to Item 3.0.

Name, title, institution	Study role(s): e.g., conduct interviews/surveys, recruit participants, obtain consent, review records, etc.
There are no items to display	

For existing protocols: Item 2.0 has been modified and this item cannot be edited. When submitting an amendment please use the information found in the text box below to complete Item 2.0 above.
Briefly describe the other study personnel.

2.1 **Indicate the human subjects research training these personnel have or will receive. If training is required in a language other than English or if research is occurring in a location where research personnel do not have access to the internet (e.g., rural community without internet capability), please describe how human subjects training requirements will be fulfilled.**

Check all that apply:

- ☐ CITI Training
- ☐ UC HIPAA Training
- ☐ Other

2.2 **If you indicated "Other" to item 2.1, describe:**

2.3 ***Will this study use the UCLA Health Sciences Volunteer Program to assist with the conduct of the research study?**
○ Yes ○ No

3.0 ***Will any of the study procedures or analyses be contracted to a consultant or an organization?**
○ Yes ◉ **No**

3.1 **If yes, specify the consultant(s) and/or organization(s) and the work that they will do for the study:**

the work that they will do for the study.

ID: IRB#17-000048 View: NEW 1.1b - Type of Study Review

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Type of Study Review

1.0 ***Indicate the level of risk involved with this study.**

(if there are multiple groups or phases associated with this study, select the highest level of risk.)

- ○ Minimal risk or no known risks - Click here for the OHRPP tip sheet on minimal risk.
- ◉ **Greater than minimal risk**

2.0 ***Indicate the type of review that you are requesting for this study.**

- ◉ **IRB Review: Expedited or Full Board**
- ○ Certification of Exemption from IRB Review

2.1 **If you indicated "IRB Review: Expedited or Full Board" as the type of review in item 2.0, select the IRB that you think best matches your research.**

	Name	Description
◉	**Medical Institutional Review Board 1**	MIRB1 reviews general and internal medicine, infectious diseases and ophthalmologic research.
○	Medical Institutional Review Board 2	MIRB2 reviews oncology and hematology research.
○	Medical Institutional Review Board 3	MIRB3 reviews neuroscience, neurology, psychiatric, drug abuse and dental research.
○	North General Institutional Review Board	NGIRB reviews research from the College of Letters & Science and the Professional Schools.
○	South General Institutional Review Board	SGIRB reviews social-behavioral research from the Schools of Public Health, Nursing, and Medicine.

***Please note*: The above requests are for initial routing purposes only. The final decision as to committee assignment and type of review, rests with OHRPP and/or the IRBs.**

3.0 ***Is this a COVID-19 research proposal that falls under the following scope:**

a. Access to the suspected and confirmed UCLA Health COVID-19 patients.
b. Access to the electronic medical record chart or data of those patients.
c. Access to the remnant or research biospecimen collection of those patients.
d. Planning any clinical research interventional trial (drug/device) for those patients.
e. COVID Population-based studies that overlap the UCLA Health population or UCLA healthcare workers.

- ○ Yes
- ◉ **No**

ID: IRB#17-000048 View: NEW 1.2 - Conflict of Interest Information

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Conflict of Interest Information

1.0 * **Does the Principal Investigator, any of the key personnel, or their spouses, registered domestic partners, or dependent children, have a financial interest in the sponsor (profit, non-for-profit) of the research?**

○ Yes ◉ **No**

1.1 **If yes, attach a completed copy of the Financial Interests Form for each person who indicates a financial or related interest:**

Document Name	Document Version #
There are no items to display	

2.0 * **Does the Principal Investigator, any of the key personnel, or their spouses, registered domestic partners, or dependent children, have any financial interests related to the research sponsored by a government agency?**

○ Yes ◉ **No**

2.1 **If yes, attach a completed copy of the Financial Interests Form:**

Document Name	Document Version #
There are no items to display	

3.0 * **Indicate whether any of these financial interests have been submitted to or reviewed by the UCLA campus Conflict of Interest Review Committee (CIRC):**

○ Yes ◉ **No**

3.1 **If you have received a response from CIRC, attach it here:**

Document Name	Document Version #
There are no items to display	

ID: IRB#17-000048 View: NEW 1.3 - Study Locations

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Study Locations

1.0 ***Indicate the locations where any research activities will be performed by the UCLA research team with participants and/or private information obtained.**

Check all that apply:

- [x] **a. UCLA Sites or UCLA Health System Sites (Does not include Harbor-UCLA Medical Center, Olive View-UCLA Medical Center, or Orthopaedic Institute for Children)**
- [ ] b. Off Campus (in California)
- [ ] c. Outside California (in the U.S.)
- [ ] d. Outside the United States ***See note at right**
- [ ] e. Internet

1.1 **If you selected b, c or d above, please provide your assurance that documentation of each site's permission to conduct the research at the site(s) will be obtained and maintained by the UCLA PI as applicable:**

Agree ☐

2.0 ***Is this a multi-institutional study (i.e., a collaborative project with other sites that have their own IRBs or principal investigators)?**

(Includes but not limited to UC MOU and CTSI MOU collaborations where UCLA IRB review is requested.)

○ Yes ◉ **No**

If no, please skip directly to the next page, do not complete the questions below.
If yes, please answer items 2.1-2.3:

2.1 **Will UCLA be responsible for the overall direction of the study at the other institutions?**

○ Yes ○ No

2.1.1 **Indicate the measures that will be taken to assure regulatory compliance at each site and that the following types of information will be communicated to the other sites: study procedures; modifications to the protocol and related documents; and safety updates, interim results and other information that may impact risks to study participants.**

Check all that apply:

- [ ] Conference calls or meetings with minutes distributed to each site
- [ ] Timely e-mail communications
- [ ] Postings on the study website
- [ ] Other

2.1.1.1 **If you chose "other", describe.**

2.1.2 **If you answered "yes" to item 2.1 above, please provide your assurance that the current IRB approval for each site(s) will be obtained and maintained by the UCLA PI as applicable:**

Agree ☐

2.2 **Will the UCLA principal investigator specified on this application be responsible for the data coordinating center?**

2.3 **Indicate the anticipated total number of study participants that will be enrolled across all of the institutions.**

ID: IRB#17-000048 View: NEW 1.4 - UCLA Sites or UCLA Health System Sites

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UCLA Sites or UCLA Health System Sites

*Please complete this section if you indicated that your study is greater than minimal risk **AND** that research activities will be performed at UCLA Sites or UCLA Health System Sites.*

1.0 ***Indicate where study procedures or data collection procedures - that are greater than minimal risk - will be conducted.**

Check all that apply:

- [ ] Clinical & Translational Research Center (CTRC)
- [x] **Inpatient Medical Facility**
- [ ] Outpatient Treatment Facility/Private Office
- [ ] Public Area
- [ ] Research Laboratory
- [ ] Other

1.1 **If you indicated "other", specify.**

2.0 ***Indicate the resources available to handle potential emergencies related to study procedures that are greater than minimal risk.**

Check all that apply:

- [ ] This item is not applicable to this study
- [x] **Basic Life Support (BLS) certified personnel**
- [x] **Advanced Cardiac Life Support (ACLS) certified personnel**
- [x] **Code Blue Team (hospital emergency response team)**
- [x] **Emergency crash cart**
- [x] **Paramedic Emergency Response Team (911)**
- [ ] Suicide Protocol
- [ ] Other

2.1 **If you indicated "other", specify.**

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Project Identification Information

1.0 ***Type of Submission (Select one)**

- (●) **Research Study**
- ( ) Application for Approval of "Research Participant Pool" or recruitment database only

2.0 ***Type of Submission (Select one)**
For Amendments, do not undo the response below. Undoing the response may remove sections of the original application.

- (●) **New Submission**
- ( ) Transfer of Ongoing Research from Another Site from Investigator moving to UCLA. Please complete Item 2.1.

2.1 **If you selected "Transfer of Ongoing Research" in Item 2.0 indicate the current status of the study and a brief summary of the work to date.**

3.0 ***Who developed this study?**

Check all that apply:

- [x] **UCLA investigator**
- [ ] Investigator from another institution
- [ ] Industry/Pharmaceutical Company
- [ ] Cooperative Group (e.g., Children's Oncology Group, AIDS Clinical Trial Group)
- [ ] Other

3.1 **If other, specify.**

4.0 **Review For and Reliance Upon External IRBs.**

***Indicate if one of the following applies to this study. (Select one)**

- (●) **None of the options apply.**
- ( ) UCLA IRB to serve as IRB of record for another institution.
- ( ) UCLA to RELY on another IRB.
  This includes reliance using UC MOU, CTSI, NCI, RAND, and Western IRBs.

5.0 ***Is this study cancer related,** including the recruitment of individuals with cancer, collection of cancer human biological samples, specimens or data, or the recruitment of individuals because they are cancer survivors or at risk of developing cancer?

( ) Yes (●) **No**

Note: If you answered "Yes", you must submit an application to the Jonsson Comprehensive Cancer Center (JCCC) Internal Scientific Peer Review Committee (ISPRC). Click here for instructions for submitting to the ISPRC. The ISPRC approval notice or letter of exemption should be attached in Section 2.1/Item 7.2 of the webIRB application.

6.0 ***Nurse Involvement:** Does this study involve any nursing time, effort, and/or resources at UCLA Health System sites, including as subjects, investigators, clinical care providers or data or specimen collectors?

( ) Yes (●) **No**

Note: If you answer "Yes", please submit an application to the Research and Innovation Council (RIC) (formerly Nursing Practice Research Council (NPRC)). For contact information or for more information about RIC and how to apply, click here. ***IRB approval is not contingent on RIC approval and you do not need to upload documentation of approval from the RIC into webIRB.***

7.0 ***Federal regulations (45 CFR 46.111) require scientific review before an IRB approves a study. For the majority of studies being reviewed and approved by the UCLA IRB, the IRB performs this review. See http://ora.research.ucla.edu /OHRPP/Documents/Policy/4/Scientific_Review.pdf for additional details.**

Do you want the IRB to consider external scientific or scholarly review?

( ) Yes (●) **No**

7.1 **If yes, indicate the source of scientific or scholarly review for the study.**

Check all that apply.

- [ ] National Institutes of Health (NIH)
- [ ] The funding agency (other than NIH)
- [ ] Faculty Sponsor
- [ ] JCCC – Internal Scientific Peer Review Committee (ISPRC)
- [ ] Clinical Translational Research Center (CTRC)
- [ ] UCLA Department
- [ ] Other

7.1.1 If you checked "other", describe.

7.2 Attach a copy of the scientific or scholarly review, if applicable.

Document Name	Document Version #

There are no items to display

ID: IRB#17-000048 View: NEW 2.2 - Lay Summary and Keywords

This view has been locked by amendment(s)

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Lay Summary and Keywords

Please provide the following information about your study.

1.0 ***Provide a brief lay summary describing this study. (limit 500 words).**

Pheochromocytoma is a catecholamine (ex. adrenaline) secreting tumor for which the primary treatment is surgical resection. Due to the hormones secreted by the tumor, alpha receptors on peripheral blood vessels are activated, causing constriction of these blood vessels and dangerously high blood pressure. During resection of the tumor, the source of excess hormone secretion is abruptly removed, which can lead to life-threatening blood pressure fluctuations during surgery.

Alpha blockers are a class of medication that blocks the alpha receptor on blood vessels. Given preoperatively over a few weeks, these medications negate the effects of the excess hormones secreted by the pheochromocytoma, reducing the frequency and severity of dangerous blood pressure fluctuations intraoperatively and postoperatively. Preoperative alpha blockade is therefore critical to safely perform surgery to resect pheochromocytoma.

Phenoxybenzamine, a non-selective alpha blocker, is the most common medication used to alpha block patients prior to pheochromocytoma resection. However, due to increasing drug costs and increased side effects in comparison with selective alpha blockers, there is a renewed interest in studying alternatives to phenoxybenzamine.

Selective alpha blockers such as doxazosin are also commonly used to alpha block patients prior to pheochromocytoma resection. Selective alpha blockers are significantly less expensive and are associated with fewer side effects than phenoxybenzamine. Most retrospective studies comparing phenoxybenzamine with selective alpha blockers show no difference in intraoperative blood pressure fluctuations, morbidity, or mortality in pheochromocytoma resection.

The purpose of our study is to analyze preoperative, intraoperative, and postoperative outcomes in patients undergoing pheochromocytoma resection. We will compare a prospective group of patients who receive doxazosin (selective) for alpha blockade prior to surgery to a retrospective group of patients who received phenoxybenzamine (non-selective). Outcomes will include postoperative morbidity and mortality, intraoperative hemodynamic instability, quality of life, and cost.

2.0 ***List three to five keywords describing this study (separate the words with commas). The keywords may be used for identifying certain types of studies.**

pheochromocytoma, alpha blocker, randomized controlled trial

3.0 * **Is this study conducted or supported by HHS (e.g., the National Institutes of Health, Centers for Control and Prevention, etc.)?**

○ Yes ◉ **No**

4.0 * **Is this study regulated by the Food and Drug Administration (FDA)?**

◉ **Yes** ○ No

4.1 **If yes, check all that apply:**

- ☑ **Human Drugs**
- ☐ Medical Devices
- ☐ Biological Products
- ☐ Mobile Medical Applications
- ☐ Food Additives
- ☐ Color Additives
- ☐ Other

ID: IRB#17-000048 View: NEW 2.3 - Methods/Procedures - Descriptors

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Methods/Procedures - Descriptors

Note: The items listed below are not an inclusive list of methods and procedures that may be used in research studies. The list only includes items that will trigger additional questions related to the research or are needed for the review process

1.0 ***Indicate all that apply to this study.**

- [ ] Audio, Visual or Digital Recordings
- [ ] Certificate of Confidentiality for research not supported by NIH
- [ ] Clinical Trial of a Drug, Biologic, Device or a Behavioral Intervention
- [ ] Community Based Research
- [ ] Controlled Substances (Schedule I or II)
- [ ] Deception or Partial Disclosure
- [ ] Devices/Diagnostics (Note: Submit all HUDs in BruinIRB)
- [x] **Drugs/Biologics/Dietary Supplements**
- [ ] Genetic Analyses/Genotyping
- [ ] Human Embryonic Stem Cells and/or Induced Pluripotent Stem Cells
- [ ] Human Gene Transfer/ Recombinant DNA
- [ ] Infectious Agents
- [ ] Non-FDA approved medical equipment used with UCLA hospital patients or research participants that operate under the UCLA Hospital License.
- [ ] Radiation (Standard of Care or Investigational Use of radioactive materials, radiation producing machines or ionizing radiation)
- [ ] Substance Abuse Research (with Medication)
- [ ] Treatment in an Emergency Setting (with request to waive consent)
- [ ] **None of the above**

2.0 ***Will the study require services or resources owned/rented/operated or provided by the UCLA Health System (e.g. clinic and/or hospital visit(s), CTRC, professional medical services, clinical treatment, diagnostics, labs, medical supplies, etc.)?**

Please direct any questions about this to The Financial Coverage & Activation Team at coverageanalysis@mednet.ucla.edu.

○ Yes ◉ **No**

ID: IRB#17-000048 View: NEW 6.1 - Funding and Other Study Characteristics

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Funding and Other Study Characteristics

1.0 ***Indicate the funding status for this study**.

- ○ Funded
- ○ Application for funding is pending
- ◉ **Departmental funding / Self funding / No funding**

2.0 ***Check all that apply**:

- ☐ The research will be conducted through the UCLA Clinical and Translational Research Center (CTRC)
- ☐ The study will be supported by or conducted in collaboration with the U.S. Department of Defense (DOD)
- ☐ The study will be supported by or conducted in collaboration with the U.S. Department of Energy (DOE)
- ☐ The study will be supported by or conducted in collaboration with the U.S. Department of Justice (DOJ)
- ☐ The study will be supported by or conducted in collaboration with the U.S. Department of Education (ED)
- ☐ The study will be supported by or conducted in collaboration with the U.S. Department of Protection Agency (EPA)
- ☑ **None of the above**

2.1 **If you selected DOD, DOE, DOJ, ED, and/or EPA support/collaboration, please provide your assurances that you will review the additional requirements for research supported by the relevant federal agency.**

Agree ☐

Note: Please refer to the Federally-Supported Research section of the OHRPP guidance document: Funding Considerations for Federally-Funded and Industry-Sponsored Human Research.

ID: IRB#17-000048 View: NEW 8.1 - Study Design

This view has been locked by amendment(s)

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Study Design

1.0 ***Check all that apply to the study design.**

- ☐ **Direct subject contact ONLY** – The research activities involve direct contact with study participants (e.g., collection of data or specimens in person or via internet, phone, mail, etc.)
- ☐ **No direct subject contact** – None of the research activities involve direct contact with study participants and include only analyses of data, records and/or human biological specimens (e.g., medical record or other record review, study of specimens left over from clinical procedures).
- ☑ **BOTH Direct subject contact AND No direct subject contact – Some of the research activities involve direct contact with study participants and some of the research activities involve analyses of data, records and/or human specimens obtained without contact with participants.**

ID: IRB#17-000048 View: NEW 8.6 - Drugs/Biologics/Dietary Supplements

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Drugs/Biologics/Dietary Supplements

You indicated that this study includes drugs/biologics/dietary supplements (section 2.3/item 1.0). Please provide the following information.

1.0 Approved Drugs or Biologics: List any drugs or biologics that will be used in this study in accordance with their approved labeling.

The UCLA Pharmacy will not dispense drugs that have been procured from an external pharmacy or compounding pharmacy. Contact the UCLA Pharmacy - Investigational Section at (310) 267-8522 if you require a compounded drug for the study.

Phenoxybenzamine, doxazosin

2.0 Enter any drugs/biologics that will be used as part of this study that do not fit in response to item 1.0 above.

Generic name of the drug/biologic	Investigational Drug/Biologics Information
There are no items to display	

3.0 All drugs and biologics for research at UCLA are to be managed through the UCLA Pharmacy. Provide your assurance that you have or will submit an Investigational Drug Study application to the Pharmacy.

Agree ☑

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Information about Study Data

This information is needed to determine how you will best protect the confidentiality of data.

1.0 ***Indicate all that apply to the study data.**

Check all that apply:

- [x] **Obtained from a medical or clinical record**
- [x] **Created or collected as part of health or mental health care**
- [ ] Used to make healthcare or mental healthcare decisions and/or provided to other healthcare professionals
- [ ] Research data will be entered into the participants' medical or clinical record
- [ ] **None of the above**

2.0 ***Is it reasonably foreseeable that the study will collect information that State or Federal law requires to be reported to other officials (e.g., child or elder abuse), ethically requires action (e.g., suicidal ideation), or is a reportable disease?**

- ○ Yes
- ◉ **No**

2.1 **If yes, explain below and include a discussion of the reporting requirements in the consent document:**

3.0 ***Indicate if any of the following are being obtained and used without any direct contact with study participants.**

- [ ] Records (Not medical)
- [ ] Human biological specimens
- [x] **None of the Above**

4.0 *Indicate all identifiers that may be **accessed or included in the research records** for the study**:**

- [x] **Names**
- [x] **Dates**
- [x] **Age (if over 89 years)**
- [x] **Postal Address**
- [x] **Phone Numbers**
- [ ] Fax Numbers
- [x] **E-Mail Address**
- [ ] Social Security Number
- [x] **Medical Record Number**
- [x] **Health Plan Numbers**
- [x] **Account Numbers**
- [ ] License/Certificate Numbers
- [ ] Vehicle ID Numbers
- [ ] Device Identifiers/Serial Numbers
- [ ] Web URLS
- [ ] IP Address Numbers
- [ ] Biometric Identifiers (including finger and voice prints)
- [ ] Facial Photos/Images
- [ ] Any Other Unique Identifier (this does not include the code assigned by the investigator to identify the data)
- [ ] **None of the above**

4.1 **If social security numbers will be collected explain why they are necessary, how they will be used, how they will be protected and how long they will be retained.**

5.0 ***Select all that apply:**

- [x] **The data and/or specimens will be directly labeled with personal identifying information when acquired by the investigator for this research**
- [ ] The data and/or specimens will be labeled with a code that the research team can link to personal identifying information when acquired by the investigator for this research

the investigator for this research

- [ ] The 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 when acquired by the investigator for this research
- [ ] The data are restricted use data (A term used in Social-Behavioral research. See guidance on the right.)

5.1 Indicate how the data will be used when this study is completed.

Check all that apply:

- [x] **Use for this study**
- [x] **Use for possible future research**
- [ ] Use to create a bank or repository at UCLA
- [ ] Add to existing repository
- [ ] Other

5.1.1 If Other, specify:

ID: IRB#17-000048 View: NEW 9.2a - Privacy and Confidentiality

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Privacy and Confidentiality

Important Notes:

- **Privacy is about people.** Privacy refers to a person's wish to control the access of others to themselves.
- **Confidentiality is about data.** Confidentiality refers to the researcher's plan to handle, manage, and disseminate the participant's identifiable private information.

See OHRPP Quick Guide: Protecting Privacy and Maintaining Confidentiality

1.0 *Privacy: How will the investigator maintain privacy in the research setting(s)? (e.g., interviewing participant in a room or area where conversations cannot be overheard by others, or conducting medical procedures in an examination room, or behind a curtain in an emergency room).

All activities which include direct patient contact with be conducted as part of our usual standard of practice. The study will be discussed with potential participants in a private room or area where conversations cannot be overheard by others.

2.0 *Confidentiality: If the protocol will collect and maintain identifiable data, explain how the planned safeguards to maintain confidentiality of identifiable data and data security are appropriate to the degree of risk from disclosure.

Note: Other sections of the application (e.g., Sections 9.3, 9.3a, 9.4, 9.5, and 15.3) will request specifications such as identification of persons who will have access to code keys or measures to comply with HIPAA requirements.

The data will be encrypted and stored in REDCap. Access to the REDCap database will be restricted to study investigators.

ID: IRB#17-000048 View: NEW 9.3 - Data Security

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Data Security

You indicated that the study team will have access to personally identifiable or coded information (Section 9.2/item 5). Please complete the following items.

1.0 ***Do you agree to follow the OHRPP Data Security in Research guidance and procedures?**

- (●) **Yes**
- ( ) I have an alternate equally effective plan (*Note: The plan must be attached to item #2.1*)

2.0 ***Do you have a data security plan for this study?** *(Note: a plan is not required for all studies; it may be recommended in some instance).*

(●) **Yes** ( ) No

2.1 **If yes, attach it here:**

Document Name	Document Version #
Redcap	0.01

3.0 ***Indicate all that apply to personally identifiable information or codes during conduct of the study:**

- [x] **The data and/or specimens will be coded**
- [ ] The personal identifying information will be removed and destroyed
- [ ] Personally identifying information will be maintained with the data and/or specimens

3.1 **If you indicated that the personal identifying information will be removed or destroyed or that the data/specimens will be coded, provide the following information:**

- **The process for removing and destroying the personal identifying information or for coding the information, and**
- **Indicate who will perform the task**

Data will be stored on RedCap utilizing a non-identifying record ID. Associated personal identifying information including Name, MRN, and date of birth, etc. will be destroyed at the end of the study by study personnel.

4.0 ***Will coded or personally identifiable data be collected, transmitted or stored via the internet?**

(●) **Yes** ( ) No

4.1 **If yes, indicate all that apply:**

- [ ] A mechanism such as Survey Monkey, Zoomerang, or an e-mail anonymizing service will be used to strip off the IP addresses for data submitted via e-mail.
- [x] **The data will be encrypted.**
- [ ] A firewall will be used to protect the research computer from unauthorized access.
- [ ] Controlled access privileges will be used on the hardware storing the data.
- [ ] Other.

4.1.1 **If you indicated "Other", describe:**

5.0 ***Provide your assurances that if there is a data security breach for this study, the PI will notify the IRB and your department's IT Compliance Coordinator.**

Agree [x]

ID: IRB#17-000048 View: NEW 9.4 - Data Security Plan - During the Study

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Data Security Plan - During the Study

You indicated that data and/or specimens for this study will be coded (Section 9.3/item 3). Please complete the following information.

1.0 During the study indicate **how data will be stored and secured** including paper records, electronic files, audio/video tapes, specimens. Specify how the **code key** will be securely maintained, as applicable.

Check all that apply:

1.1 ***Electronic Data**

- [x] **Encryption or password protection software will be used**
- [x] **Secure network server will be used to store data**
- [ ] Stand alone desktop computer will be used to store data (not connected to server/internet)
- [ ] A contracted outside vendor will store the code key. The vendor will have a business associate agreement with UCLA.
- [ ] Other
- [ ] **Not Applicable**

1.2 ***Hardcopy Data, Recordings and Specimens**

- [x] **Locked file cabinet or locked room with limited access by authorized personnel**
- [ ] Locked lab/refrigerator/freezer with limited access by authorized personnel
- [ ] The code key will be kept in a locked file in a locked room
- [ ] The coded data and/or specimens will be maintained in a different room
- [ ] Other
- [ ] **Not Applicable**

1.3 **If you indicated "Other" in item 1.1 or 1.2 above, describe here.**

2.0 ***By checking this box, I provide my assurance that all the person(s) who will have access to the code key have been identified in section 1.1 or section 1.1a.**

Agree [x]

ID: IRB#17-000048 View: NEW 9.5 - Data Security Plan

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Data Security Plan

You indicated that the study will have access to personally identifiable or coded information (Section 9.2/item 5). Please complete the following items:

1.0 ***After the study is completed**, indicate how the data codes and/or personal identifying information will be handled.

Check all that apply:

- [x] **All data files will be stripped of personal identifiers and/or the key to the code destroyed.**
- [ ] All specimens will be stripped of personal identifiers and/or the key to the code destroyed.
- [ ] Personal identifiers and/or codes linking the data and/or specimens to personal identifiers will be maintained for future research.
- [ ] Audio or Video recordings will be transcribed and then destroyed or 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.
- [ ] Restricted use data will be destroyed or returned to the source.

1.1 **If you indicated that personal identifiers will be maintained for future research, provide the following information:**
a) How the information will be securely handled and stored
b) assure confidentiality, and
c) who will have access to the identifiers and/or codes.
Once the research described in this study is completed, we will destroy the key linking patient names and identifiers to the data used for analysis. The de-identified data or spreadsheet used for analyses will be retained for 1-2 years after the study results are published.

2.0 **Describe any additional steps, if any, to be taken to assure that the subjects' identities and any personal identifying information are kept confidential.**

ID: IRB#17-000048 View: NEW 9.6 - Use of Data and/or Specimens without Direct Contact

This view has been locked by amendment(s)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Use of Data and/or Specimens without Direct Contact

You indicated that some or all of the research activities do not involve direct contact with study participants (Section 8.1/item 1.0). Please provide the following information.

1.0 If **all** of your research activities are without direct contact with study participants, provide the following information:

1.1 **Indicate the purpose of the research, specifying the problems and/or hypotheses to be addressed**:
The purpose of our study is to analyze preoperative, intraoperative, and postoperative outcomes in patients treated with selective (doxazosin) or non-selective (phenoxybenzamine) alpha blockade prior to pheochromocytoma resection. Outcomes will include postoperative morbidity and mortality, intraoperative hemodynamic instability, quality of life, and cost.

We hypothesize that doxazosin is not inferior compared to phenoxybenzamine in terms of postoperative morbidity and mortality, intraoperative hemodynamic instability, quality of life, and cost.

1.2 **Describe the study design and proposed data analyses**:
Given the difficulty in randomizing patients (high cost of phenoxybenzamine has caused a large portion of patients crossing over to the doxazosin arm, resulting in unbalance between the number of patients in each arm), patients who have been pre-treated with doxazosin before pheochromocytoma resection prospectively followed during the course of this study will be compared to a retrospective group of patients who were pre-treated with phenoxybenzamine.

Descriptive statistics including mean, median, standard difference, and frequencies will be calculated for each of the variables measured.

Differences in hemodynamic instability as indexed by specific vital sign parameters, ICU length of stay, inpatient length of stay, morbidity, mortality, cost, and quality of life will be analyzed with t tests or non-parametric tests as appropriate.

1.3 ***If you will conduct genetic analysis with specimens, provide your assurance that the results will not be disclosed to subjects or used for clinical care.**

- (●) **Agree**
- ( ) Not Applicable

2.0 ***Describe specimens and/or data that will be acquired without direct contact with study participants. Complete this item for each type used in the study:**

	Source	Data and/or Specimens Information
View	UCLA medical records	

Data and/or Specimens? Indicate all that apply:	Data
Indicate whether the data and/or specimens are pre-existing, at the time of this study, and/or if collection will be prospective:	Pre-existing
Describe the data and/or specimens and indicate the original collection dates:	Electronic medical records from patients undergoing adrenalectomy for pheochromocytoma or paraganglioma from January 1, 2015 to present. Please see item 4.0 for further details on data to be collected from the EMR.
Indicate the approximate number of data records and/or specimens to be collected:	50
Will the specimens be used with animals?	No
If yes, indicate the IACUC Number:	*No Value Entered*

3.0 ***If any sources of data and/or specimens are not at UCLA, provide your agreement that the appropriate institutional approvals for release will be obtained** (e.g., IRB approval).

- (●) **Agree**

- (●)
- ( ) Not Applicable

If you plan to send UCLA Health data to third parties, please contact the CTSI for directions about additional requirements. https://www.ctsi.ucla.edu/researcher-resources/pages/third_party

4.0 Attach any data abstraction tools or lists with the data elements to be collected.

Document Name	Document Version #
Study variables	0.01

If you will access information from UCLA Health records, attach a copy of your completed UCLA EHR Data Abstraction template for research. For more information see: https://ctsi.ucla.edu/researcher-resources/pages/datarequests

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Data and/or Specimens for Possible Future Use

You indicated that prospectively collected data and/or specimens would be stored for future use (Section 9.2/item 5.1). Please provide the following information.

1.0 *Specify what information directly or indirectly linked to the subject will be provided with data and/or specimens to other investigators.

Check all that apply:

- [ ] No subject identifiers (The data/specimens are anonymous; no one including the investigator could identify the person from whom the materials were gathered.)
- [ ] The data will be coded (A code links the data/specimens to the study participants. A key to the code exists.)
- [ ] Personal Identifying Information
- [x] **Not applicable, the data will not be shared outside the study team.**

2.0 Distribution Rules: Describe the criteria used to determine the adequacy of requests to obtain data and/or specimens (e.g., the type of researchers that will be eligible to receive data):

This view has been locked by amendment(s)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Study Summary - Research Study

1.0 Study Materials: As applicable to this study, attach the following:

- **Protocol, Dissertation Proposal or Study Plan**
- **Preliminary Data**
- **Surveys, Questionnaires or other instruments to be used with study participants**
- **References**

Document Name	Document Version #
Alpha blockade in pheochromocytoma RCT survey draft.pdf	0.01
Kiernan-2014-Predictors of hemodynamic instabi.pdf	0.01
Medication and Blood Pressure Log v2.docx	0.01
Protocol for Preoperative Alpha Blockade Titration V2.docx no comments.docx	0.02
Prys-Roberts-2002-Efficacy and safety of doxaz.pdf	0.01
Randle-2016-Selective Versus Non-selective alp.pdf	0.01
Study variables	0.01
Timeline.docx	0.01
Weingarten-2010-Comparison of two preoperative.pdf	0.01

2.0 *Specific Aims: Indicate the purpose of the research, specifying the problems and/or hypotheses to be addressed.

The purpose of our study is to analyze preoperative, intraoperative, and postoperative outcomes in patients treated with selective (doxazosin) or non-selective (phenoxybenzamine) alpha blockade prior to pheochromocytoma resection. Outcomes will include postoperative morbidity and mortality, intraoperative hemodynamic instability, quality of life, and cost.

3.0 *Background and Significance: Provide a summary of the background for this study and explain how it will contribute to existing knowledge.

For greater than minimal risk biomedical studies, include preliminary data. If necessary, attach in Item 1.0 graphs or tables used to convey information. If there no preliminary data are available, briefly indicate why this proposed study is a reasonable starting point.

Pheochromocytoma is a catecholamine (ex. adrenaline) secreting tumor for which the primary treatment is surgical resection. Due to the hormones secreted by the tumor, alpha receptors on peripheral blood vessels are activated, causing constriction of these blood vessels and dangerously high blood pressure. During resection of the tumor, the source of excess hormone secretion is abruptly removed, which can lead to life-threatening low blood pressure in the absence of preoperative alpha blockade.

Alpha blockers are a class of drug that blocks the alpha receptor on blood vessels. Given preoperatively over a few weeks, these drugs negate the effects of the excess hormones secreted by the pheochromocytoma, reducing the frequency and severity of dangerous blood pressure fluctuations intraoperatively and postoperatively. Preoperative alpha blockade is therefore critical to safely perform surgery to resect pheochromocytoma.

Phenoxybenzamine, a non-selective alpha blocker, is the most commonly used drug used to alpha block patients prior to pheochromocytoma resection. However, due to increasing drug costs and increased side effects in comparison with selective alpha blockers, there is a renewed interest in studying alternatives to phenoxybenzamine.

Selective alpha blockers such as doxazosin are also commonly used to alpha block patients prior to pheochromocytoma resection. Retrospective studies comparing phenoxybenzamine with selective alpha blockers suggest that the use of selective alpha blockers does not lead to additional morbidity or mortality in pheochromocytoma resection. However, no prospective, randomized controlled trials comparing phenoxybenzamine to selective alpha blockers have been performed.

Our study to our knowledge will represent the first prospective, randomized controlled trial comparing selective and non-selective alpha blockade in resection of pheochromocytoma.

4.0 *Research Design and Methods: Describe in detail the design and methodology of the study.

PATIENT ACQUISITION. All patients referred to the UCLA Department of Surgery requiring surgical resection of pheochromocytoma or paraganglioma will be counseled about surgery and the necessity for preoperative alpha blockade. The benefits and risks of the study will discussed, and the patient will be given the opportunity to enroll. Upon obtaining informed consent regarding enrollment in the study, the patient will be randomized to either receive preoperative blockade with either phenoxybenzamine or doxazosin.

PREOPERATIVE PREPARATION. The patient will then be referred to the UCLA Preoperative Evaluation and Planning Center (PEPC) for preoperative planning and optimization by an attending anesthesiologist. Additional testing such as echocardiography or stress testing will be pursed in accordance with preoperative risk-stratification in the standard fashion. A few weeks prior to surgery, the patient will initiate preoperative alpha blockade with the drug as determined by randomization. The drug will be titrated to a blood pressure of 120-130/80-85 in the standard fashion. Adjunctive beta blockers or calcium channel blockers may be initiated at the discretion of the physician.

Titration will be performed utilized the attached log ("Medication and Blood Pressure Log"), which will be emailed to the patient and will be returned by the patient by email every 2 days. The patients sitting and standing blood pressure will be used to titrate their alpha blocker dosage to pre-specified targets as noted in the original IRB proposal. Heart rate will be logged to determine whether the patient requires adjunctive

specified targets as noted in the original IRB proposal. Heart rate will be logged to determine whether the patient requires adjunctive antihypertensive medications such as beta blockers or calcium channel blockers. This titration will take place over a period of 2-3 weeks. Once the patient's alpha blockade titration is complete, the log will be saved in a secure, encrypted server and will be linked with the patients record using non-identifying record ID.

INTRAOPERATIVE PROTOCOL. Intraoperative hemodynamic monitoring will be conducted in the standard fashion, and a phenylephrine dose response curve will be generated by titration with phenylephrine to estimate the ED30 and therefore the effectiveness of the blockade. Surgery will proceed in the standard fashion. Times of induction, tumor manipulation, and adrenal vein ligation will be recorded. Vasopressors will be used at the discretion of the anesthesiologist.

POSTOPERATIVE PROTOCOL. Patients will be taken to the PACU for routine postoperative care. Admission to the surgical ICU will be performed at the discretion of the attending anesthesiologist and surgeon.

QUALITY OF LIFE / DRUG ADVERSE EFFECTS. Data regarding patient health related quality of life and drug adverse effects will be collected at five time points pre-blockade, post-blockade, and postoperatively at 3 months, 6 months, and 1 year. Health related quality of life data will be assessed utilizing the Short Form-36. Patients will be queried to specific adverse effects such as nasal congestion, headaches, palpitation, as well as their frequency and level of distress caused. Surveys will be complete in person during routine encounters or over the phone.

COST. Preoperative drug costs will be determined using the average wholesale price per unit multiplied by the number of units taken by the patient. Enrollment of the patient in Medicare and Medicare part D will be noted. Data regarding out of pocket drug costs will be collected. Inpatient costs will be calculated utilizing patient charges and the application of a charge to cost ratio.

4.1 * **Will you be providing results of any experimental tests that are performed for the study?**

- ○ Yes - Complete Items 4.1.1 and 4.1.2
- ○ No
- ◉ **Not Applicable**

4.1.1 **You indicated in Item 4.1 that the research involves experimental tests. Please describe the tests, provide a rationale for providing participants with the experimental test results and explain what, how and by whom participants and their health care provider will be told about the meaning, reliability, and applicability of the test results for health care decisions.**

4.1.2 **Will tests be performed by a Clinical Laboratory Improvement Amendments (CLIA) approved lab?**

○ Yes ○ No

5.0 ***Indicate how much time will be required of the subjects, per visit or contact, and in total for the study.**

The time required of study subjects will includes time that will be standard for the care of the patient and unrelated to participation of the study. This involves preoperative evaluation by a surgeon (30 minutes) and anesthesiologist (30 minutes), inpatient surgery and routine inpatient postoperative care (average length of inpatient stay 2-3 days), and postoperative follow up (30 minutes).

Additional time required of the study subjects as related to the study would involve 5 questionnaires administered in person or by phone at the time points outlined above, with each administration of the survey taking approximately 5 minutes.

6.0 ***Statistics and Data Analysis: Describe the proposed statistical procedures or descriptive analyses for the study. If applicable, indicate how the sample size was determined.**

Descriptive statistics including mean, median, standard difference, and frequencies will be calculated for each of the variables measured.

Differences in hemodynamic instability as indexed by specific vital sign parameters, ICU length of stay, inpatient length of stay, morbidity, mortality, cost, and quality of life will be analyzed with t tests or non-parametric tests as appropriate.

This view has been locked by amendment(s)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Characteristics of the Study Population

1.0 ***Is this an observational or ethnographic study for which the number of participants observed or interviewed cannot be determined in advance.**

○ Yes ◉ **No**

2.0 **If you answered "no" to item 1.0, indicate the maximum number of study participants you hope to enroll:**

62

3.0 **How many participants do you expect you will need to recruit, consent and/or screen to meet the target number above?**

73

4.0 ***Indicate the specific inclusion criteria for enrollment of each of the groups of research participants in this study.**
If there are any inclusion criteria based on *gender, pregnancy/childbearing potential, race, ethnicity or language spoken*, explain the nature of and scientific rationale for the inclusions.

Inclusion criteria include:
(1) Diagnosis of pheochromocytoma or paraganglioma as evidenced by appropriate biochemical evaluation and imaging.
(2) Surgical resection recommended.
(3) Patients aged 12 and older.

5.0 ***Indicate the specific exclusion criteria for each of the groups of research participants in this study.**
If there are any exclusion criteria based on *gender, pregnancy/childbearing potential, race, ethnicity or language spoken*, explain the nature of and scientific rationale for the exclusions.

None.

6.0 ***How (chart review, additional tests/exams for study purposes, etc.), when and by whom will eligibility be determined?**

Eligibility for the study will be evaluated during the time of surgical consultation by review of prior medical records including biochemical tests and imaging by the attending surgeon.

We expect 100% of patients evaluated for pheochromocytoma resection will be eligible for the study.

Assuming an enrollment rate of 85%, 73 patients will have to be screened to meet our target sample size of 62 patients.

ID: IRB#17-000048 View: NEW 11.2 - Characteristics of Study Population

This view has been locked by amendment(s)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Characteristics of Study Population

1.0 ***Indicate the age range of the study participants.**

Check all that apply:

- [ ] 0 to 6 years
- [ ] 7 to 11 years
- [x] **12 to 17 years**
- [ ] 17 or younger **in California** who can consent for themselves - see note below
- [ ] 17 or younger **outside California** who can consent for themselves - see note below
- [x] **18 years or older**

NOTE:

- For additional information on minors **in California** who are permitted to consent for themselves please refer to the section "Legal Exceptions Permitting Certain Minors to Consent" in the OHRPP Guidance document, Child Assent and Permission by Parents or Guardians
- For additional information on minors **outside of California** who are permitted to consent for themselves please refer to the section "Exceptions Outside of California" in the OHRPP Guidance document, Child Assent and Permission by Parents or Guardians

2.0 ***Indicate if any of the following populations/specimens will be specifically recruited/obtained for the study.**

- [x] **Adults who are competent to give informed consent**
- [ ] Adults unable to give informed consent
- [ ] Adults with diminished capacity to consent
- [ ] Fetal Tissue
- [ ] Neonates
- [ ] Participants Unable to Read, Speak, or understand English
- [ ] Pregnant Women/Fetuses
- [ ] Prisoners
- [ ] UCLA Faculty/Staff
- [ ] UCLA Students
- [ ] Wards
- [ ] **Unknown/Not Applicable**

3.0 * **Is it possible that there may be non-English speakers enrolled in this study or children whose parents are non-English speaking?**

(●) **Yes** ( ) No

ID: IRB#17-000048 View: NEW 12.1 - Children (Minors)

This view has been locked by amendment(s)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Children (Minors)

You indicated that children will participate in the study (Section 11.2/item 1.0). Please provide the following information.

1.0 ***Choose the description that is applicable to this study:**

- ☐ The research does not involve greater than minimal risk (45 CFR 46.404/21 CFR 50.51)
- ☑ **The research involves greater than minimal risk, but presents the prospect of direct benefit to individuals (45 CFR 46.405/21 CFR 50.52)**
- ☐ The research involves greater than minimal risk and no prospect of direct benefit to individual subjects, but it likely to yield generalizable knowledge about the subject's disorder or condition (45 CFR 46.406/21 CFR 50.53)
- ☐ The research does not fall under any of the above categories, but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. (note: after IRB review, studies in this category must be sent to the Secretary, HHS for a determination)(45 CFR 46.407/21 CFR 50.54)

2.0 **If you selected more than one description, indicate the groups of children involved in the study and the category for each group.**

3.0 ***Provide justification for involving Minors in this research (check all that apply).**

- ☐ The primary focus of the study is children and/or adolescents
- ☐ This is a study about a disease or condition that specifically affects children
- ☑ **Other**

3.1 **If you checked "other," describe.**
This is a study about a disease or condition that affects both adults and children.

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Risks & Benefits

Benefits

1.0 ***Are there any potential direct benefits (physical, psychological, social or other) to study participants?**

○ Yes ◉ **No**

1.1 **If yes, describe.**

2.0 ***Describe the potential benefits to society including the importance of the knowledge to be gained.**

Currently, the evidence regarding selective vs. non-selective alpha blockade prior to pheochromocytoma resection is based retrospective data. No prospective, randomized controlled trials have been performed. The potential benefits to society of a prospective, randomized controlled trial of selective vs. non-selective alpha blockade prior to pheochromocytoma resection include those related to patient cost and quality of life.

(1) Cost. The cost of prescription drugs in the United States is increasing, with the cost of some drugs increasing by over 1000% in the last decade.[1] Currently, the maximum listed wholesale price per unit of phenoxybenzamine is $197.79 in contrast to $1.42 for doxazosin[2]. In our anecdotal experience, an increasing number of patients are unable to afford phenoxybenzamine for preoperative alpha blockade prior to pheochromocytoma resection. As current studies show no differences in morbidity and mortality between selective and non-selective alpha blockade prior to pheochromocytoma resection, doxazosin is likely to represent a clinically equivalent option associated with significant cost savings.

(2) Quality of life. Phenoxybenzamine is a long-acting, non-competitive, non-selective alpha blocker that crosses the blood brain barrier, causing centrally mediated side effects including headaches and sedation that limit the medication's tolerability. Patients who receive doxazosin in comparison to phenoxybenzamine prior to pheochromocytoma resection less frequently experience postural hypotension, nasal stuffiness, and headache.[3] In addition to being cost effective, doxazosin may also be associated with increased health related quality of life while receiving alpha blockade.

Overall, current retrospective data suggest that selective alpha blockade is as effective as non-selective blockade in addition to being less costly and associated with less frequent adverse effects. A randomized controlled trial demonstrating this will result in societal cost savings and increased health related quality of life in patients undergoing pheochromocytoma resection.

[1] Kesselheim AS, Avorn J, Sarpatwari A. The High Cost of Prescription Drugs in the United StatesOrigins and Prospects for Reform. JAMA. 2016;316(8):858-871. doi:10.1001/jama.2016.11237
[2] http://micromedex.com/Portals/1/Assets/AWP%20Policy_Oct%202014.pdf
[3] Prys-Roberts C, Farndon JR. Efficacy and safety of doxazosin for perioperative management of patients with pheochromocytoma. World J Surg. 2002;26(8):1037-1042.

Risks

3.0 ***Indicate the potential risks/discomforts, if any, associated with each intervention or research procedure.**

Additionally discuss any measures that will be taken to minimize risks. If data are available, estimate (a) the probability that a given harm may occur, (b) its severity, and (c) its potential reversibility. The information provided should be reflected in risks section of the informed consent documents.

If this is an exempt study and there are no risks, indicate N/A. Otherwise, please see the help text.

The potential risks of the study include the following:

LOSS OF CONFIDENTIALITY: Although patient identifiers and data will be stored on a secure server with limited access, basic contact information such as the patient's name, address, and telephone number may be at risk if the server is compromised.

STANDARD OF CARE DRUG RISKS: Since both drugs are standardly used to prepare patients for pheochromocytoma surgery, participating in this research study will not expose patients to additional risks beyond what is considered standard of care. Studies comparing phenoxybenazime and doxazosin have mostly shown no difference in blood pressure fluctuations during surgery.

Risk/Benefit Analysis

4.0 ***RISKS/BENEFIT ANALYSIS: Indicate how the *risks to the participants are reasonable in relation to anticipated benefits*, if any, to participants and the importance of the knowledge that may reasonably be expected to result from the study:**

Current retrospective data suggest that selective alpha blockade is as effective as non-selective blockade in addition to being less costly and associated with less frequent adverse effects. A randomized controlled trial demonstrating this will result in societal cost savings and increased health related quality of life in patients undergoing pheochromocytoma resection.

Alternatives

5.0 ***Indicate the alternatives to participating in this study.**

Check all that apply.

- [x] **All types of studies - Choose not to participate in the study**
- [ ] Clinical/Intervention Studies - Receive standard of care instead of participating in the study
- [ ] Clinical/Intervention Studies - Medication, device, or other treatment is available off study
- [ ] Item is Not Applicable (e.g., study of existing data)
- [ ] Other

5.1 **If "other" was selected, specify.**

5.2 **If this is a clinical/intervention study:**

Describe the standard of care or activities at UCLA (or study site) that are available to prospective participants who do not enroll in this study. If not applicable to your study, state not applicable (N/A).

ID: IRB#17-000048 View: NEW 15.1 - Data & Safety Monitoring Plan

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Data & Safety Monitoring Plan

1.0 ***Is a Data and Safety Monitoring Plan (DSMP) required by the funding agency or other entity?**

○ Yes ◉ **No**

ID: IRB#17-000048 View: NEW 15.2 - Data & Safety Monitoring Plan (continued)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Data & Safety Monitoring Plan (continued)

Important Note:
All interventional studies involving more than minimal risk must include a Data and Safety Monitoring Plan (DSMP). A DSMP is a plan established to assure that each research study has a mechanism for appropriate oversight and monitoring of the conduct of the study to ensure the safety of participants and the validity and integrity of the data. The DSMP should indicate specifically whether or not there will be a formal Data Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC).

Most, but not all studies (i.e., non-interventional studies) undergoing full board review will require a DSMP. You will need a DSMP if any of the following apply:
1. This is a Phase I, II or III clinical trial
2. This is an investigator initiated trial (Section 2.1/item 3.0)
3. This study involves treatment in an emergency setting (Section 2.3/item 1.0)
4. A Data/Safety Monitoring Plan is required by the funding agency (Section 15.1/item 1.0)
5. This study is greater than minimal risk (Section 1.1b/item 1.0)

1.0 ***Indicate who will be responsible for overseeing the study safety. Check all that apply.**

- [x] **The Principal Investigator**
- [ ] Designee of the Principal Investigator
- [ ] The DSMP includes at least one person who is not associated with the study
- [ ] A formally constituted Data and Safety Monitoring Board (DSMB)
- [ ] Medical monitor designated by the sponsor
- [ ] Other

1.1 **If you indicated that a designee would be responsible for overseeing the study safety, or that the DSMP would include at least one person not associated with the study, provide the name(s) of this individual (s). Also, provide a brief explanation of why this person(s) would be appropriate in this role(s).**

1.2 **If you indicated "other," describe or indicate where the information can be found in the attached protocol.**

2.0 ***Provide your assurance that information about serious, unanticipated problems related to the study (e.g., adverse events, incidents and violations) will be reported to the IRB within the time frames specified by the Summary Sheet of Reporting Requirements.**
Agree ☑

Provide the following information as appropriate to the study:

3.0 ***Are there plans to perform an interim safety analysis?**
◉ **Yes** ○ No

3.1 **If yes, describe or indicate where the information can be found in the attached protocol.**
Interim safety analysis will be performed at the point at which 50% of the targeted cohort has been followed-up for 30 days.

4.0 ***Have stopping rules been established for the study?**
◉ **Yes** ○ No

4.1 **If yes, describe or indicate where the information can be found in the attached protocol.**
The primary outcomes that will be compared at the interim safety analysis include postoperative morbidity as manifested by rates of stroke and myocardial infarction as well as postoperative mortality within 30 days. Rates of stroke, myocardial infarction, and mortality will be compared with the chi square test and the study will be stopped if a significant difference is found with a threshold of $P < 0.05$.

5.0 ***Are there defined rules for withdrawing participants from study interventions?**
○ Yes ◉ **No**

○ Yes ◉ **No**

5.1 **If yes, describe or indicate where the information can be found in the attached protocol.**

ID: IRB#17-000048 View: NEW 16.1 - Payment, Costs, and Injury

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Payment, Costs, and Injury

1.0 ***Indicate what the participants will receive for their participation in the study.**

Check all that apply.

- [x] **No payment will be provided**
- [ ] University check
- [ ] Course Credit
- [ ] Cash
- [ ] Gift Cards/Bruincard Deposit
- [ ] Non-Monetary Gifts or Services
- [ ] Other (including vouchers for parking)

1.1 **If you selected Non-Monetary Gifts or Services or Other, describe:**

1.2 **If you selected *Cash* and/or *Gift Cards/Bruincard Deposit* please specify the estimated total amount of money you will require to pay all participants during the length of the entire study. This information is required by UCLA Business and Finance Services (BFS), the office that will provide the cash/gift cards for payment.**

2.0 **If study participants will receive financial or other payment for their participation in the study, please provide the following information:**

- If applicable, the amount each participant will receive and the payment schedule to be followed including whether partial payment will be provided when the participant does not complete the study.
- If there are different plans for different populations or sub-studies, specify the groups and describe the plans.
- If families or children will be involved in the research, clarify how the payments, items or services will be apportioned.

3.0 ***Will subjects** incur **any financial obligations from participation in the study?**

- ○ Yes
- ◉ **No**

3.1 **If yes, describe:**

4.0 ***Indicate below that you are familiar with UCLA policy related to treatment and compensation for injury and that you will use in the consent form for this study the appropriate UC required statement describing "Treatment and Compensation for Injury." Click here to access the UCLA policy: Treatment and Compensation for Research Related Injury.**

Note: Select **Not Applicable** if study is minimal risk.

- ◉ **Agree**
- ○ Not Applicable

ID: IRB#17-000048 View: NEW 17.1 - HIPAA Authorization

This view has been locked by amendment(s)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

HIPAA Authorization

According to your responses to section 9.2/item 1.0, this study uses protected health information. Please provide the following information.

1.0 ***Indicate all that apply to use of or disclosure of PHI in this study:**

- [x] **All UC participants will sign a UC HIPAA Research Authorization for Release of Personal Health Information for Research.**
- [ ] **Another Institutions' Healthcare Authorization** for Release of Health Information will be used **or a waiver** for release of health information will be granted **from another Institution**.
- [x] **A Waiver of HIPAA Research Authorization is requested for screening using UC medical records. I assure that the PHI collected for this study will not be reused or disclosed, except as indicated in this application.**
- [x] **A Total Waiver of HIPAA Research Authorization is requested for the entire study. I assure that the PHI collected for this study from UC records will not be reused or disclosed, except as indicated in this application.**
- [ ] **Limited Data Set with a Data Use Agreement** will be obtained from UC medical records. I assure that I will follow the data security plan outlined in this application to protect the identifiers from improper use or disclosure.
- [ ] **None of the above. This study will be conducted outside the United States**

If you will access information from UCLA Health records, additional permissions are required. These permissions are described at: https://ctsi.ucla.edu/researcher-resources/pages/datarequests

1.1 Please identify the persons who will access UC Health records:

- ○ CTSI Informatics Program Staff (https://ctsi.ucla.edu/researcher-resources/pages/datarequests)
- ○ Key personnel listed in Section 1.1/5.0

2.0 ***Indicate to whom or where you will grant access to personal identifying information (including PHI) as part of the study process:**

- [x] **There is no plan to share identifiers outside the study team**
- [ ] The study sponsor; on site only (if there is more than one study sponsor, specify below).
- [ ] A foreign country or countries
- [ ] Other

2.1 If you checked "other", "a foreign country or countries", or if "there is more than one sponsor", specify.

3.0 ***The investigator's agreement is needed to the following:**

- The protected health information requested is the minimum necessary to meet the research objectives

- The protected health information that is obtained as part of this study will not be used or disclosed to any other person other than study personnel or to the parties listed in item Section 17.1/item 2, except as required by law.

- Study Sponsors will **not** be provided with personal identifying information (including PHI) to take from the study site at any time, including the end of the study.

- Data and specimens shared with outside entities, such as study sponsors, will be coded or de-identified.

Agree [x]

ID: IRB#17-000048 View: NEW 17.2 - HIPAA - Waiver of Authorization

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

HIPAA - Waiver of Authorization

According to your responses to Section 17.1/item 1, a waiver of authorization is requested. Please provide the following information.

In addition to the information that will be requested later in this application for a waiver of informed consent, HIPAA requires the following information for a waiver of authorization:

1.0 ***Indicate why the research could not be practicably conducted without access to and use of the protected health information.**

Check all that apply.

- [x] **The PHI is needed to identify potential participants with a specific medical condition**
- [ ] It would not be feasible to individually contact the large numbers of potential subjects in the study
- [ ] It would not be possible to locate many of the individuals whose records would be used for the study
- [ ] Many of the individuals, whose records would be used for the study, are now deceased
- [ ] Other

1.1 **If you checked "other", specify.**

ID: IRB#17-000048 View: NEW 18.1 - Identification/Recruitment Methods

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Identification/Recruitment Methods

1.0 ***How will you identify and/or recruit participants for this study.**

Check all that apply:

- [ ] Advertisements/Flyers/Information Sheet/Internet Postings
- [x] **Direct recruitment of potential study participants (e.g., physicians talking with their own or clinic patients about the study, contact between the study team and potential subjects in person, on the phone or on the internet, etc.)**
- [ ] Random or Other Probability Sampling
- [ ] Recruitment Letters/Emails
- [ ] Referrals (e.g., referrals from non-investigator healthcare providers, snowball sampling, participants referring other participants, etc.)
- [x] **Review of medical records to identify potential research participants**
- [ ] Review of publicly available records
- [ ] Review of other records
- [ ] Participant pool for which potential research participants have given permission for future contact
- [ ] Potential Study Participants are identified from another IRB approved study or IRB approved screening protocol
- [ ] Other

ID: IRB#17-000048 View: NEW 18.2 - Recruitment Methods

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Recruitment Methods

1.0 Please upload copies of your recruitment materials below. This includes advertisements, flyers, internet postings, recruitment scripts and letters/emails.

Document Name	Document Version #
There are no items to display	

Ads/Flyers/Info Sheets/Internet Postings

2.0 If you have indicated that study participants will be recruited with advertisements/flyers (Section 18.1/Item 1.0), please indicate the type of media that will be used (e.g., newspaper, radio, internet, etc.) and/or where information will be posted or distributed.

Direct Recruitment

3.0 If you have indicated that participants will be recruited through direct contact (Section 18.1/Item 1.0), please provide the following information:

- A description of how, when, and where initial contact would be made (e.g. in a public setting, in a waiting room, via a phone call, via a letter, via the internet, etc.)
- If applicable to the study, indicate how the potential research participant's privacy will be maintained.
- Who will make the contact (e.g. the investigator, a patient's physician, etc.)

If a patient meets inclusion criteria for the study, the study will be discussed with the patients at the time of surgical consultation in a private exam room by the attending surgeon.

If a patient has been already evaluated for surgery but has not yet received surgery and the study has not been introduced, a phone call will be made to the patient to discuss the study over the phone.

3.1 If you will be directly recruiting potential participants who are your patients, students, laboratory workers or any others with whom you have a relationship of authority or unequal power, describe what measures you will put in place to avoid those approached from feeling pressured or unduly influenced to participate in the study.
We will let the patients know that their participation is voluntary and will not affect our clinical relationship or their treatment options.

Recruitment Letters/Emails

4.0 If you have indicated that recruitment letters will be distributed to participants (Section 18.1/item 1.0), please indicate who will send out the recruitment letter (i.e. will it be the investigator or other persons who have authorized access to the information), how inquiries will be handled, and if there will be follow-up contacts.

Referrals

5.0 If you have indicated that study participants will be identified from referrals (Section 18.1/item 1.0), please indicate the source of the referral (e.g., friends, other participants, healthcare providers) and how the referral will be elicited.

Research Participant Pools/Recruitment Databases

6.0 If you have indicated that subjects will be identified and recruited from a subject pool(s) or recruitment database, (Section 18.1/item 1.0), please indicate the name of the Pool or Recruitment Database and UCLA Department. If the Pool or Recruitment Database is not at UCLA, identify the location.

ID: IRB#17-000048 View: NEW 18.7 - Review of Medical Records

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Review of Medical Records

1.0 ***You have indicated that potential research participants will be identified from medical records (Section 18.1/item 1). Indicate the specific records to be reviewed and the information that will be obtained to identify potential participants for this study.**

Potential research participants will be identified at the time of their surgery consultation.

The records to be reviewed to identify potential participants for this study include those that would be reviewed in the standard surgical consultation in patients undergoing evaluation for pheochromocytoma resection including laboratory tests and imaging.

No review of medical records beyond what is required for a standard surgical consultation will be required.

1.1 **If you have a data sheet summarizing the information that will be obtained from the records, you can upload it here instead of listing the information above.**

Document Name	Document Version #
There are no items to display	

Federal and State Regulations require that the IRB review the information below to determine if a waiver of consent and authorization is appropriate for use of medical record information for recruitment purposes.

2.0 ***Do you assure the following?**

- The information that will be reviewed is the minimal necessary to identify potential research participants for this research.
- The information that will be obtained for identification of participants will not be reused or disclosed outside the research team, except as required by law.
- All study personnel will comply with HIPAA regulations.
- Review of the medical records will not result in greater than minimal risk by taking appropriate precautions to protect the confidentiality of the information.

Agree ☑

3.0 ***Indicate why the potential study participants' rights and welfare would not be adversely affected by waiving consent to review their medical records.**

Check all that apply.

- ☑ **Precautions will be taken to protect the confidentiality of the research participants**
- ☑ **The information from the medical records will not be used in any way other than to identify potential research participants**
- ☐ Other

3.1 **If other, describe**

4.0 ***Indicate why the research could not practicably be carried out without a waiver of consent.**

Check all that apply.

- ☑ **The identities of the potential study participants who would meet the criteria for this study would not be known without access to their medical records**
- ☐ Other

4.1 **If other, specify**

5.0 **NON-UC INSTUTITION(S) / AGENCY(IES) HIPAA POLICIES AND PROCEDURES**

If your research will involve access, use, or disclosure of PHI held by a non-UC institution/agency, please provide your assurances that you will comply with that (those) instutition(s)/agency(ies)' HIPAA policies and procedures.

Agree ☐

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Eligibility Screening

1.0 ***Will you be conducting a preliminary assessment with potential research participants to determine study eligibility during the recruitment process?**

○ Yes ◉ **No**

ID: IRB#17-000048 View: NEW 20.1 - Informed Consent Process

This view has been locked by amendment(s)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Informed Consent Process

You indicated that adults (and/or minors who are permitted to consent for themselves) are participating in the study (Section 11.2/item 1.0 or Section 12.2/item 1.0).

For additional information on minors who are permitted to consent for themselves please refer to the section "Legal Exceptions Permitting Certain Minors to Consent" in the OHRPP Guidance document, Child Assent and Permission by Parents or Guardians.

1.0 ***Indicate your plans for obtaining informed consent for this study.**

Check all that apply:

☑ **Signed consent will be obtained from the research participant or Legally Authorized Representative.**

- **Signed consent means research participants will be asked to sign and date a written consent form.**

☐ **A waiver of signed consent is requested for the entire study.** One of the following procedures will be conducted:

- **A written information sheet will** be used. Signed consent will not be obtained from research participants.
- **Oral consent** will be obtained from the research participant or Legally Authorized Representative (LAR)
- This option should be selected if the study involves consenting participants via the internet.

☑ **A waiver of consent is being requested.**

- **Research participants will not be asked to sign a consent form or give oral consent**

☐ Consent will be obtained by a collaborating institution.

1.1 **- If you checked more than one plan above, list the study groups and the plan that you will use for each.**
- If you checked "Consent will be obtained by a collaborating institution", explain the consent process and upload a copy of the most recent approved consent document in item 1.2.

Signed consent obtained from patients who were randomized to phenoxybenzamine or doxazosin.

Requesting a waiver of consent for the retrospective cohort of patients who were pre-treated with phenoxybenzamine.

1.2 **If applicable, attach the consent document(s) from collaborating institution(s).**

Document Name	Document Version #
There are no items to display	

ID: IRB#17-000048 View: NEW 20.3 - Description of the Consent Process

This view has been locked by amendment(s)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Description of the Consent Process

1.0 ***Indicate the type of setting(s) in which the consent process will be conducted.**

Check all that apply.

- [ ] In a private home
- [x] **In a private room**
- [ ] In a waiting room
- [ ] In a public setting
- [ ] In a group setting
- [ ] On the internet
- [x] **Over the telephone**
- [ ] Other

1.1 **If you checked more than one response, or indicated other, describe.**

If a patient meets inclusion criteria for the study, the study will be discussed with the patients at the time of surgical consultation in a private exam room by the attending surgeon and informed consent obtained at that time.

If a patient has been already evaluated for surgery but has not yet received surgery and the study has not been introduced, a phone call will be made to the patient by an MD to discuss the study over the phone. The patient will be mailed a consent form to either return by mail or in person at their next visit.

All patients enrolled in the study will have had an in person encounter with an attending surgeon prior to obtaining consent.

1.2 **If the setting is not private, describe the measures to protect confidentiality or indicate "not applicable."**

2.0 ***Indicate the measures that will be taken to provide prospective research participants with sufficient opportunity to consider whether or not to participate in the study.**

Check all that apply.

- [x] **Member(s) of the study staff will meet with the prospective participants/families to review the consent document(s) and/or provide an oral explanation of the study. Individuals will be given a chance to ask questions before making a considered decision about whether or not to participate in the study.**
- [x] **Prospective participants/families will have the opportunity to take the consent form(s) home and may discuss the documents with others prior to deciding whether or not to participate in the study.**
- [x] **Prospective participants will self-administer the consent and send it back if they decide to participate in the study.**
- [ ] Other

2.1 **If you indicated other, describe.**

3.0 ***Indicate the length of time subjects are given to decide whether they wish to participate in the study.**

Patients will have approximately 1-2 weeks from the time of their initial surgical consultation to decide whether they wish to participate in the study.

4.0 ***How will you assess whether subjects understand the information conveyed during the consent process?**

Check all that apply.

- [ ] Use the Subject Comprehension Tool form for research
- [x] **Investigator or study team member will evaluate during the consent process**
- [ ] Other
- [ ] Not Applicable

4.1 **If you indicated other, describe.**

5.0 ***Attach copies of the informed consent documents, information sheets, consent scripts as applicable to this study. Include copies of**

5.0 ***Attach copies of the informed consent documents, information sheets, consent scripts as applicable to this study. Include copies of translated forms, if applicable.**

Document Name	Document Version #
Alpha blockade in pheochromocytoma RCT consent form v4.doc	0.02
Blood pressure log	0.01

ID: IRB#17-000048 View: NEW 20.4 - Request to Waive Informed Consent for the Study

This view has been locked by amendment(s)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Request to Waive Informed Consent for the Study

You indicated that you are requesting a waiver of consent (Section 20.1/item 1). The following information is needed.

1.0 ***Does this study pose more than minimal risk?**

○ Yes ◉ **No**

2.0 ***Would the participants' rights and welfare be adversely affected by waiving consent?**

○ Yes ◉ **No**

3.0 ***Explain why the research could not practicably be carried out without the waiver of consent.**

Check all that apply.

- ☑ **It would not be possible to contact all of the participants associated with the data or specimens to obtain consent**
- ☐ The design of the study does not allow the possibility of obtaining consent
- ☑ **The size of the potential study population is so large that it would not be feasible to obtain consent**
- ☐ Requiring informed consent may introduce systematic bias into the data
- ☐ The risk of contacting the participants is greater than the risk of the study procedures
- ☐ Other

3.1 **If you indicated that the study design does not allow the possibility of obtaining consent, or that requiring consent may introduce systematic bias or checked "other", provide any information that may assist the IRB to understand why obtaining consent would not be feasible.**

4.0 ***Would it be appropriate to provide participants with information about the study after their participation?**

Check all that apply.

- ☐ No, the data will not be stored with identifiers with which to contact the participants
- ☑ **No, the information that is found will have no impact on treatment or care**
- ☐ No, there is not a feasible mechanism by which to notify participants/respondents
- ☐ No, other
- ☐ Yes
- ☐ **Not Applicable** - analysis of secondary data

4.1 **If you checked "no other," specify.**

4.2 **If you indicated "yes," indicate the information that would be provided and the mechanism.**

ID: IRB#17-000048 View: NEW 21.1 - Permission/Assent Process - Minors

This view has been locked by amendment(s)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Permission/Assent Process - Minors

You indicated that minors are participating in the study (Section 11.2/Item 1.0 or Section 11.2/Item 2.0). Please provide the following information.

1.0 ***Indicate your plans for obtaining assent and parental permission for this study.**

Check all that apply.

- [x] **Signed assent will be obtained from all minors**
- [ ] Signed assent will be obtained for some minors
- [ ] Minors will receive an oral explanation of the study, a written information sheet, or both and will not be asked to sign an assent form.

- [x] **Signed permission will be obtained from the parent or guardian**
- [ ] Request to waive assent for this study; parental permission will be obtained.
- [ ] Parents will receive an oral explanation of the study, written information sheet or both and will not be asked to sign a permission form.
- [ ] Request to waive parental permission for this study; assent will be obtained
- [ ] Request to waive **both** Parental Permission and Assent

- [ ] Consent will be obtained by a collaborating institution.

1.1 **- If you will use different plans for obtaining assent and/or permission with different groups of participants, list the groups and plans here.**
- If you checked "Consent will be obtained by a collaborating institution", explain the consent process and upload a copy of the most recent approved consent document in Item 1.2.
12 year old subjects will sign the child assent form and 13-17 years old subjects will sign the youth assent form.

1.2

Document Name	Document Version #
There are no items to display	

***Note**: If there is more than one group of minors participating in the study with varying degrees of risk, you may be presented with more than one screen requesting information on plans to obtain parental permission.*

ID: IRB#17-000048 View: NEW 21.8 - Parental Permission (Research Greater than Minimal Risk with Prospect of Direct Benefit - 45 CFR 46.405/21 CFR 50.52)

This view has been locked by amendment(s)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Parental Permission (Research Greater than Minimal Risk with Prospect of Direct Benefit - 45 CFR 46.405/21 CFR 50.52)

You indicated that you will be obtaining parental permission for this study (Section 21.1/item 1.0) and that the study meets criteria greater than minimal risk with the prospect of direct benefit – 45 CFR 46.405/21 CFR 50.52 (Section 12.1/item 1). Please provide the following information.

1.0 ***Choose one of the following.**

- (●) **Permission from one parent is sufficient. Given the nature of the study, it is not likely to provoke disagreement between the parents about their child's participation**
- ( ) Permission from both parents will be obtained if both are reasonably available.

2.0 ***Indicate how parental permission and assent will be obtained taking into account the age of the child, risk of the study and if steps will be taken to assure that the child will be given an independent opportunity to consider study participation.**

Check all that apply.

- [x] **The study will be discussed with the child and parent together before conducting the permission and assent processes**
- [ ] Parental permission will be obtained before the child is approached for assent
- [ ] Assent will be obtained before the parents are approached for permission
- [ ] Only parental permission will be obtained

2.1 **If you checked more than one choice above explain why. (For example, the decision of how to handle the assent and permission process may depend on an assessment of the family dynamics or the ages of the children involved in the study).**

ID: IRB#17-000048 View: NEW 21.11 - Description of the Permission/Assent Process

This view has been locked by amendment(s)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Description of the Permission/Assent Process

1.0 ***Indicate the type of setting(s) in which the assent/permission process will be conducted.**

Check all that apply.

- [ ] In a private home
- [x] **In a private room**
- [ ] In a waiting room
- [ ] In a public setting
- [ ] In a group setting
- [ ] On the internet
- [ ] Over the telephone
- [ ] Other

1.1 **If you indicated more than one response or other, describe.**

1.2 **If the setting is not private, describe the measures to protect confidentiality or indicate "not applicable."**

2.0 ***Indicate the measures that will be taken to provide prospective research participants with sufficient opportunity to consider whether or not to participate in the study.**

Check all that apply.

- [x] **Member(s) of the study staff will meet with the prospective participants/families to review the assent/permission document(s) and/or provide an oral explanation of the study. Individuals will be given a chance to ask questions before making a considered decision about whether or not to participate in the study.**
- [ ] Prospective participants/families will have the opportunity to take the assent/permission form(s) home and may discuss the documents with others prior to deciding whether or not to participate in the study.
- [ ] Prospective participants will self administer the assent/permission and study measures (e.g., assent/permission forms and surveys that are sent through the mail or internet).
- [ ] Other

2.1 **If you indicated other or checked more than one response, describe.**

3.0 ***Indicate the timing of the assent/permission process with respect to initiation of the study procedures.**

Check all that apply.

- [x] **Procedures will commence after the assent/permission form(s) are signed or oral permission/assent is provided.**
- [ ] Participants/families will be allowed a period of time to consider participation in the study.

3.1 ***Indicate the amount of time between the assent/permission process and initiation of the study procedures (e.g., 4 hours, overnight, etc.)**
Time between assent/permission process and initiation of study procedures will be the time between the clinic visit and the time the patient starts the preoperative blockade medication. Typically 1 or 2 days.

4.0 ***How will you assess whether subjects understand the information conveyed during the assent/permission process?**

Check all that apply.

- [ ] Use the Subject Comprehension Tool form for research
- [x] **Investigator or study team member will evaluate during the consent process**
- [ ] Other
- [ ] Not Applicable

4.1 **If you indicated other, describe.**

5.0 **Attach copies of the parental permission forms, assents forms, information sheets, screening or scripts as applicable to this study. Include copies of translated forms, if applicable.**

Document Name	Document Version #
Child_Assent_v1.doc	0.02
Parent_Perm_v1.doc	0.03
Teen_Assent_v1.doc	0.02

ID: IRB#17-000048 View: NEW 22.1 - Cultural Considerations

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Cultural Considerations

The following items are designed to acquaint the IRB with cultural features of the population that you are studying that may require procedures to ensure truly informed consent.

1.0 ***Check all that apply to the population(s) with which this study will be conducted.**

- [ ] Participants may be illiterate or insufficiently literate to be able to comprehend a conventional written informed consent form.
- [ ] The participants may be reluctant or unwilling to sign a written informed consent form.
- [ ] The husbands make decisions for their wives.
- [ ] Elders make decisions for younger adult family members.
- [ ] Elders make decisions for their community.
- [ ] It is considered impolite to refuse a request.
- [ ] People are fearful of refusing requests that they regard as coming from authorities.
- [x] **None of the above are applicable to this study.**

1.1 **If any of the above items are applicable to this study, indicate the steps that you will take to ensure voluntary participation after providing the study information, and if applicable, any planned involvement with the community regarding the consent process.**

ID: IRB#17-000048 View: NEW 22.2 - Non-English Speaking Study Participants

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Non-English Speaking Study Participants

You indicated that you would involve non-English speaking participants in the study (Section 11.2/Item 2.0) and/or that there is a possibility that non-English speaking participants may be enrolled in the study (Section 11.2/Item 3.0). Please provide the following information.

1.0 ***Indicate the method that you use to conduct the consent process[1] with participants who do not speak English.**

Check all that apply.

- [x] **The consent form and other study documents will be available in the participants' primary language. Study personnel (or qualified translators) able to discuss the participation in the patients' language will be present for the consent process.**
- [x] **Study staff or qualified translators will discuss the study in the participants' language.**
- [ ] An oral consent process will be used. Study personnel (or qualified translators) able to discuss the participation in the participants' language will be present for the consent process.
- [ ] The short form or another method will be used to conduct the consent process.

Important Note: The short form may be used in very limited circumstances. For additional information please refer to the " 'Short Form' Method" section of the OHRPP guidance document, Research Involving Non-English Speaking Research Participants.

1.1 **If you checked "short form or another method", provide additional details.**

2.0 ***How will you maintain the ability to communicate with non-English speakers throughout their participation in the study? Indicate "N/A" if not applicable to your study.**
Qualified translators will be used to communicate with participants in accordance with UCLA standards.

3.0 ***If you are conducting research for which there is a real or foreseeable risk of biomedical harm in the state of California, indicate your agreement that you will provide the participants who do not read, speak, or understand English a copy of the Research Participants Bill of Rights in a language in which they are fluent. Translations into the most common languages in the greater Los Angeles area are available for download on the OHRPP website.**

- ○ Agree
- ◉ **Not Applicable**

[1] *If minors are involved in the study, this would also include the processes of obtaining parental permission and assent, as applicable.*

ID: IRB#17-000048 View: NEW 24.0 - Additional Information and/or Attachments

This view has been locked by amendment(s)

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Additional Information and/or Attachments

1.0 **Attach any other documents that have not been specifically requested in previous items, but are needed for IRB Review.**

Document Name	Document Version #
JustinLee_CITItraining.pdf	0.02
JustinLee_UCLA HIPAA.pdf	0.01

2.0 **If there is any additional information that you want to communicate about this study, include it in the area provided. Note: this section should not be used instead of the standard application items.**

ID: IRB#17-000048 View: NEW 100.0 - Instructions for Study Submission

Instructions for Study Submission

You have completed your application, **but it has *not yet been submitted*.**

FOLLOW THESE STEPS TO SUBMIT THE APPLICATION TO THE IRB FOR REVIEW:

1. Click the **Finish** button to return to exit the SmartForm and return to the study workspace.
2. Use the **View SmartForm Progress** function to make sure that the application is complete.
3. If you are the PI or PI Proxy, click **Submit Study** under **My Activities**. If you are a member of the study team, you can let the PI know that the study is ready to submit by clicking **Send Ready Notification.**
4. Once the study is submitted, the state indicator at the top of the page will no longer display **Pre-Submission.**
5. After submission of the study, the **PI Assurances** activity will immediately become available under **My Activities**. The PI should provide his/her assurances at that time. If the PI is not available, the study can be submitted by a PI Proxy and the assurances provided at a later time. The study will be reviewed by the IRB while the **PI Assurances** are pending; however, it will not be approved until the **PI assurances** are completed.
6. ***If there is a Faculty Sponsor for the study***: The study can not be submitted to the IRB until the Faculty Sponsor provides his/her assurances through **FS Assurances** activity.

ID: IRB#17-000048 View: Display - Method Description

Audio, Visual or Digital Recordings

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000048 View: Display - Method Description

Certificate of Confidentiality for research not supported by NIH

The Certificate of Confidentiality button in this section is only if your study is NOT supported or conducted by NIH but you will obtain a Certificate of Confidentiality (for example, for studies collecting information about illegal drug use).

If you previously checked this box for an NIH-supported study before the policy change, you do not need to change your response here.

Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect the privacy of research subjects by protecting investigators and institutions from being compelled to release information that could be used to identify subjects with a research project. Certificates of Confidentiality are issued to institutions or universities where the research is conducted. They allow the investigator and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

Effective October 1, 2017, NIH has updated its policy for issuing Certificates of Confidentiality for NIH-funded and conducted research. For information about the policy change or about obtaining Certificates for research supported by other agencies, please see https://humansubjects.nih.gov/coc/index.

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000048 View: Display - Method Description

Clinical Trial of a Drug, Biologic, Device or a Behavioral Intervention

A clinical trial is a research study designed to answer specific questions about medical or behavioral treatments. The trial may be interventional or observational. Interventional studies are those in which the research participants are assigned by the investigator to a treatment or other intervention, and the outcomes measured. Observational studies are those in which individuals are observed and the outcomes are measured by the investigators.

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000048 View: Display - Method Description

Community Based Research

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000048 View: Display - Method Description

Controlled Substances (Schedule I or II)

Check here only if you are using a Schedule I or II Controlled substance in this study. Research using Schedule I or Schedule II controlled Substances must be submitted to the Research Advisory Panel of California for review and approval prior to initiation. Research using Schedule III, IV, or V Controlled Substances as a study drug do not require review by the Research Advisory Panel. For further information see: http://ag.ca.gov/research/guide.php o Schedule I Controlled Substances are drugs or substances with a high potential for abuse, that have no currently accepted medical use in treatment in the United States. Examples of Schedule I Controlled Substances are: heroin, lysergic acid diethylamide (LSD), methylenedioxy-methamphetamine (MDMA), marijuana, and psilocybin. o Schedule II Controlled Substances are drugs or substances with a high potential for abuse, that have a currently accepted medical use in treatment in the United States, or a currently accepted medical use with severe restrictions. Examples of Schedule II Controlled Substances are: fentanyl, methadone, methylphenidate, morphine, and oxycodone. For further information see: http://www.deadiversion.usdoj.gov/schedules/index.html

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000048 View: Display - Method Description

Deception or Partial Disclosure

Deception includes withholding information about the real purpose of the study or purposely giving subjects false information about some aspect of the research to prevent bias. Some professions, such as the American Psychological Association (APA) have ethical codes regarding the use of deception in research. (See sections 8.07 and 8.08 at http://www.apa.org/ethics/code/index.aspx#807) If deception is included in the study, you must also apply for approval of a waiver of the informed consent process (Section 20.1) in addition to selecting the other consent procedures planned for the study (e.g., written or oral consent).

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000048 View: Display - Method Description

Devices/Diagnostics (Note: Submit all HUDs in BruinIRB)

A medical device is defined, in part, as any health care product that does not achieve its primary intended purposes by chemical action or by being metabolized. Medical devices include, among other things, surgical lasers, wheelchairs, sutures, pacemakers, vascular grafts, intraocular lenses, and orthopedic pins. Medical devices also include diagnostic aids such as reagents and test kits for in vitro diagnosis (IVD) of disease and other medical conditions such as pregnancy. For further information see: http://www.fda.gov/oc/ohrt/irbs/irbreview.pdf

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000048 View: Display - Method Description

Drugs/Biologics/Dietary Supplements

- Drug: The term "drug" means: articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and articles (other than food) intended to affect the structure or any function of the body of man or other animals.
- Biologics vs. Drugs: Most drugs consist of pure chemical substances and their structures are known. Most biologics, however, are complex mixtures that are not easily identified or characterized. Biological products differ from conventional drugs in that they tend to be heat-sensitive and susceptible to microbial contamination. This requires sterile processes to be applied from initial manufacturing steps. For more information see: http://www.fda.gov/consumer/updates/biologics062608.html#drugs
- Dietary Supplements are products that are intended to supplement the diet and have one of the following ingredients:
  - A vitamin
  - A mineral
  - An herb or other botanical
  - An amino acid
  - A dietary substance for use by man to supplement the diet by increasing the total daily intake
  - A concentrate, metabolite, constituents, or an extract of combinations of these ingredients.

For additional information see: http://www.foodsafety.gov/~dms/supplmnt.html

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000048 View: Display - Method Description

Genetic Analyses/Genotyping

Genetic analyses/genotyping include, but are not limited to, studies of inheritable conditions or traits, gene markers or mutations, and pedigrees.

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000048 View: Display - Method Description

Human Embryonic Stem Cells and/or Induced Pluripotent Stem Cells

Research with human embryonic stem cells (hESC) and related lines requires IRB review under the following conditions: o Clinical research in which human subjects are given hESCs or related products. o When the UCLA research team will have a research related direct interaction or intervention with the cell donors, including donation of blastocysts or gametes for the purpose of creating hESCs,. o Cells provided to the UCLA research team that have identifiers or codes that can be linked back to the donor. Research involving hESC requires review and approval by the ESCRO Committee. For further information see: http://www.stemcell.ucla.edu/research

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000048 View: Display - Method Description

Human Gene Transfer/ Recombinant DNA

Studies involving gene transfer and/or recombinant DNA require approval of the UCLA Institutional Biosafety Committee (IBC). Human gene transfer is an investigational method for correcting defective genes responsible for disease development through one of the following techniques: o A normal gene may be inserted into a nonspecific location within the genome to replace a nonfunctional gene. o An abnormal gene could be swapped for a normal gene. o The abnormal gene could be repaired through selective reverse mutation, which returns the gene to its normal function. o The regulation of a particular gene could be altered. Recombinant DNA molecules, according to the NIH Guidelines, are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000048 View: Display - Method Description

Infectious Agents

Studies involving the use of Risk Group 2 or 3 infectious agents (such as bacteria, fungi, parasites, prions, rickettsia, viruses, etc.) require approval of the UCLA Institutional Biosafety Committee (IBC).

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000048 View: Display - Method Description

Non-FDA approved medical equipment used with UCLA hospital patients or research participants that operate under the UCLA Hospital License.

Clinical Engineering is responsible for completing incoming inspections on investigational devices that are used to diagnose, treat or monitor a patient and that are used in the patient care area on site at UCLA, but *not* in other hospitals such as Cedars Sinai, CHLA, or Drew. If a device is FDA and/or testing - laboratory approved for the purpose it was designed, then evaluation is not required of the device. If you have a copy of an inspection report from Clinical Engineering, please attach here. As appropriate, please contact Clinical Engineering at 310-267-9000 to arrange an inspection.

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000048 View: Display - Method Description

Radiation (Standard of Care or Investigational Use of radioactive materials, radiation producing machines or ionizing radiation)

Note: This includes CT-guided biopsy, fluoroscopy use, etc.; MRI is not included. The radiological procedures included in this study must be described in the SafetyNet system. Please create a new SafetyNet application after submitting this webIRB application to the IRB for review.

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000048 View: Display - Method Description

Substance Abuse Research (with Medication)

Research for the treatment of controlled substance addiction or abuse that uses any drug (scheduled or not) as treatment, requires the review and approval of the Research Advisory Panel of California prior to initiation. For further information see: For further information see: http://ag.ca.gov/research/guide.php

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000048 View: Display - Method Description

Treatment in an Emergency Setting (with request to waive consent)

Federal regulations allow certain research activities to be conducted in emergency settings with waiver of informed consent - in the interest of facilitating potentially life-saving and life-enhancing research with protecting the rights and welfare of participants. For further information see: o OHRP Guidance: http://www.hhs.gov/ohrp/humansubjects/guidance/hsdc97-01.htm o FDA Guidance: http://www.fda.gov/oc/ohrt /irbs/except.html

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000048 View: Display - Method Description

None of the above

Click "OK" below to return to the SmartForm page where you can select the appropriate response.

ID: IRB#17-000048 View: Specimens and/or data that will be acquired without direct contact with study participants

Specimens and/or Data that will be Acquired without direct contact with study participants

1.1 ***Data and/or Specimens? Indicate all that apply:**

- [x] **Data**
- [ ] Specimens

1.2 ***Indicate the source of the data and/or specimens. If the source is UCLA or a previous study, also indicate the IRB#:**
UCLA medical records

1.3 ***Indicate whether the data and/or specimens are pre-existing, at the time of this study, and/or if collection will be prospective. Check all that apply:**

- [x] **Pre-existing**
- [ ] Prospective

1.4 ***Describe the data and/or specimens and indicate the original collection dates. If collection is in progress, indicate the planned end date or "continuing."** (*e.g., academic records for children 6-12 years for the time period between 1995-2005, or tumor samples collected from adults between January 1, 2009 to December 31, 2009*).

Electronic medical records from patients undergoing adrenalectomy for pheochromocytoma or paraganglioma from January 1, 2015 to present. Please see item 4.0 for further details on data to be collected from the EMR.

1.5 ***Indicate the approximate number of data records and/or specimens to be collected.**
50

1.6 **If you indicated that you will be using specimens, provide the following information.**

1.6.1 **Will the specimens be used with animals?**

- ○ Yes
- ◉ **No**

1.6.1.1 **If yes, indicate the IACUC Number:**