UNIVERSITY OF CALIFORNIA, LOS ANGELES **UCLA**

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DAVID GEFFEN SCHOOL OF MEDICINE AT UCLA
CENTER FOR HUMAN NUTRITION
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November 1, 2019

PRS Reviewer

Clinicaltrials.gov

To whom it may concern

Thank you for your review of (NCT03676803, IRB# 17-000617 with most recently updated approval dated August 11, 2017) study titled “Effect of Spice Consumption on the Microbiome in Healthy Subjects: A Pilot Study”, per your request, I am submitting the IRB application.
If possible, we would like to keep this documentation confidential.

Sincerely,

Zhaoping Li, MD, PhD
Professor of Medicine
UCLA Geffen School of Medicine
Chief, UCLA Center for Human Nutrition

Date: Tuesday, October 15, 2019 12:16:07 PM

Print Close

ID: IRB#17-000617 View: NEW 1.1 - Study Title and Key Personnel

This view has been locked by amendment(s)

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

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:**
Effect of Spice Consumption on the Microbiome in Healthy Subjects: A Pilot Study

1.1 **Protocol Version Date and/or Number:**
Version 1.0, Dated 3/1/2017

2.0 ***Working or Lay Title:**
The effect of spice consumption to increase the good bacteria in the human

3.0 **Principal Investigator:**

3.1 ***Name:** ZHAOPING LI
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.
MD, PhD

3.2 **UCLA Title:** Professor of Medicine

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.**

ID: IRB#17-000617 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:** ZHAOPING LI
***Please type the Degree(s):** MD, PhD

1.2 **Principal Investigator's UCLA Department:** MEDICINE-VA WADSWORTH MED CTR

1.3 ***Protocol's UCLA Home Department:** MEDICINE-CENTER FOR HUMAN NUTRITION

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.

ID: IRB#17-000617 View: NEW 1.1b - Type of Study Review

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

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.**

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#17-000617 View: NEW 1.3 - Study Locations

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

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**
- [ ] 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

ID: IRB#17-000617 View: NEW 2.1 - Project Identification Information

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.

ID: IRB#17-000617 View: NEW 2.2 - Lay Summary and Keywords

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

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).**

This proposed pilot study will assess the ability of daily consumption of 5 grams of mixed spices to alter the gut microbiome composition compared to placebo in a free-living population. 30 subjects will be randomized to consume either 5 grams of spice or matched placebo for 2 weeks in random sequence. Stool samples will be collected at baseline and week 2 for sequencing of bacterial DNA to determine changes in the microbiota. The objective of the proposed pilot study is to determine whether intake of spice per day will alter the intestinal microflora leading to an increase in formation of short chain fatty acids. This project will provide novel preliminary data for future research studies and to develop new consumer messages on the gut health benefits of spices. New consumer information about the health benefit of spices will enhance the domestic and exported spice industry and increase consumption of spices.

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.**

Spice, Microbiome, Healthy

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#17-000617 View: NEW 2.3 - Methods/Procedures - Descriptors

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

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
- [x] **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 (including Humanitarian Devices - HUD)
- [x] **Drugs/Biologics/Dietary Supplements**
- [ ] Expanded Access to Drug, Device or Biologic for Treatment Purposes (aka Compassionate Use, Treatment Use)
- [ ] 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#17-000617

View: NEW 2.4 - Coverage Analysis

This view has been locked by amendment(s)

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

Coverage Analysis

1.0 ***Will all protocol-required items and services that produce data for the study be funded by intramural or extramural funding/support?**

- (●) **Yes - we will not bill participants or their insurers for any protocol-required items or services**
- ( ) No - we will bill one or more protocol-required items or services to participants or their insurers
- ( ) Not Applicable – this is a non-interventional study (e.g., observational/registry/retrospective study without active treatment) that does not require additional visits, labs, items or services performed solely due to study participation

Note:

*If "**Yes**" is selected to the question above, then the corresponding "Research Only" cost language in the guidance to the right should be included in the ICF, and an abbreviated coverage analysis review is indicated.*

*If "**No**" is selected to the question above, then the "Mixed Cost" language in the guidance to the right should be included in the ICF, and a full coverage analysis review is indicated.*

*If "**Not Applicable**" is selected to the question above, then coverage analysis may not be applicable, and the corresponding "All Standard of Care" cost language in the guidance on the right should be included in the ICF.*

2.0 ***Is your study any of the following?**

- **Treatment Use (Expanded Access, Compassionate Use, or a Humanitarian Use Device)**
- **Hematology-Oncology Clinical Research Unit Study**
- **UCLA reliance on an external IRB review**

(●) **Yes** ( ) No

Note: *If you have selected yes, then continue with question 3.0 below.*

3.0 **Please upload a copy of your study protocol below:**

Document Name	Document Version #
Protocol CLEAN 071017	0.02
Protocol TRACKED 071017	0.03

The following item pertains to investigational drugs and devices only.

4.0 **If the study participant or a third party payor (i.e., medical insurance/Medicare/Medicaid) may be billed for**

ID: IRB#17-000617 View: NEW 6.1 - Funding and Other Study Characteristics

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

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#17-000617 View: NEW 8.1 - Study Design

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

Study Design

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

- [x] **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#17-000617 View: NEW 8.3 - Clinical Trial of a Behavioral Intervention, Drug, Biologic or Device

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

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

You indicated that this study includes a clinical trial (section 2.3/item 1.0). Please provide the following information

1.0 ***Indicate the type of clinical trial.**

Check all that apply:

- [x] **Randomized**
- [ ] Non-randomized
- [ ] Single Blinded
- [x] **Double Blinded**
- [x] **Placebo**
- [ ] Sham Control
- [ ] Active/Treatment Control
- [ ] Open Label
- [ ] Crossover
- [ ] Washout Period
- [ ] Dose Escalation
- [ ] Other

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

2.0 ***Indicate the type of clinical trial:**

- (•) **Pilot/Feasibility**
- ( ) Phase I
- ( ) Phase I/II
- ( ) Phase II
- ( ) Phase II/III
- ( ) Phase III
- ( ) Phase III/IV
- ( ) Phase IV
- ( ) Open Label Extension/Rollover
- ( ) Expanded Access
- ( ) Behavioral

3.0 ***Indicate the status of registration of registering this trial with ClinicalTrials.gov**

ID: IRB#17-000617 View: NEW 8.6 - Drugs/Biologics/Dietary Supplements

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

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.

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
View	Spice Blend	

The trade name of the Drug/Biologic:	*No Value Entered*
Indicate the manufacturer:	McCormick Scientific Institute
Indicate the source of the study drug/biologic:	Other
If you indicated "Other" and/or that the study drug/biologic is being provided by a pharmaceutical company other than the sponsor, identify the source:	McCormick Scientific Institute
Attach the Investigator's Brochure (IB) or package insert	**Document Name**: SPICE BLEND INGREDIENT LIST **Document Version #**: 0.01
Indicate the regulatory status of the drug or biologic:	**Investigational Use of a Marketed Drug or Biologic:** The drug/biologic will be used off-label for an indication *not* in the approved labeling.
Investigational Use of a Marketed Drug or Biologic:	**Describe the approved indications for the use of the drug/biologic and how the**: Spices are generally used to flavor food products. The spice mixture in this pilot study is intended only to advance scientific understanding in the area of

ID: IRB#17-000617 View: NEW 9.2 - Information about Study Data

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:

- [ ] 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**
- [ ] Age (if over 89 years)
- [x] **Postal Address**
- [x] **Phone Numbers**
- [ ] Fax Numbers
- [x] **E-Mail Address**
- [x] **Social Security Number**
- [x] **Medical Record Number**
- [ ] Health Plan Numbers
- [ ] Account Numbers

ID: IRB#17-000617 View: NEW 9.2a - Privacy and Confidentiality

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

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 data files have safeguards to maintain the anonymity of participants and to bar unauthorized personnel. The subject forms are kept in locked files according to legal requirements.

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.

All identifiable subject data will be maintained in a private office in locked file cabinets. The research office is only accessible to research personnel.

ID: IRB#17-000617 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 #
There are no items to display	

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**

Study coordinator will label all specimens with codes only and processed internally through research labs. Paper records all contain identifying information and will be maintained in the Center for Human Nutrition under a double-locked system with restricted access by study personnel only. Paper documents may be maintained for up to three years after the completion of study, after which time they will be destroyed by shredder.

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

( ) Yes (●) **No**

ID: IRB#17-000617 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**

- ☐ Encryption or password protection software will be used
- ☑ **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**

- ☑ **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 ☑

ID: IRB#17-000617 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.**
- [x] **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.

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#17-000617 View: NEW 10.1 - Study Summary - Research Study

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 #
Bristol Srool Chair	0.01
BSQ	0.01
Protocol Clean Copy 071017	0.02
Protocol Tracked 071017	0.03
SF-36	0.01

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

Primary outcome measures:
Intestinal microbiome composition
Secondary outcome measure:
1. Fecal short chain fatty acids
2. Blood rosmarinic acid and cinnamaldehyde
3. Urine malondialdehyde (MDA)
4. Digestive Health and General Wellness questionnaires

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.

The bacterial composition of the intestinal microbiome has been linked to the development of chronic diseases including obesity, metabolic syndrome, type II diabetes and heart disease. Spices are a rich source of polyphenols and fiber. It has been demonstrated in animal studies that fruits and vegetable with high polyphenol content and fiber exhibit prebiotic effects leading to changes in the gut microbiome, decrease in symptoms of metabolic syndrome, improvement in insulin resistance and decrease in intestinal and systemic inflammation. Several human intervention studies have also been performed that demonstrated beneficial effects of high polyphenol fruits and vegetable on the intestinal microbiome. No information is available about the effect of spice consumption on the gut microbiome.

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

ID: IRB#17-000617 View: NEW 11.1 - Characteristics of the Study Population

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:**

30 subjects

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

35 subjects

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.

• Healthy human adults age 18-65 years old
• Typically consume low fiber/polyphenol diet (beige diet)

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.

• Eating a high fiber/polyphenol diet or taking any medication or dietary supplement which interfere with the absorption of polyphenols.
• History of gastrointestinal surgery, diabetes mellitus, or other serious medical condition, such as chronic hepatic or renal disease, bleeding disorder, congestive heart disease, chronic diarrhea disorders, myocardial infarction, coronary artery bypass graft, angioplasty within 6 months prior to screening, current diagnosis of uncontrolled hypertension (defined as systolic BP >160mmHg, diastolic BP > 95mmHg), active or chronic gastrointestinal disorders, bulimia, anorexia, laxative abuse, or endocrine diseases (except thyroid disease requiring medication) as indicated by medical history or routine physical examination.
• Pregnant or breastfeeding
• Currently uses tobacco products.
• Is unable or unwilling to comply with the study protocol.
• Frequently using prebiotics, probiotics, yogurt, and/or any fiber supplements
• Allergy or sensitivity to spices. Subjects will be excluded if there is a prior history of such sensitivity. Since these foods are commonly eaten and allergies are rare, subjects should be aware of this sensitivity prior to entering the study. To determine this, a positive history of spices ingestion without incident will be requested. In addition, any subject with a history of allergy or anaphylaxis of any kind will be excluded
• Taking antibiotics or laxatives within the past 3 months

ID: IRB#17-000617 View: NEW 11.2 - Characteristics of Study Population

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
- [ ] 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#17-000617 View: NEW 14.1 - Risks & Benefits

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.**

A possible benefit to society is the development of a better understanding of the role of spices and gut health. The results of this study may lead to larger studies.

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.

Mixed spice blend:
Black pepper and oregano are safe when consumed in food amounts. Cinnamon is likely safe in food amounts. Possible known side effects for consumption of ginger include heartburn, general stomach discomfort and/or diarrhea. Cayenne pepper may cause side effects such as stomach irritation and upset, sweating, flushing and runny nose. There may be unknown side effects of consumption of a blend of these spices. Subjects who are allergic to cinnamon, oregano, ginger, black pepper or cayenne pepper, should not participate in this research.

Placebo capsules:
There are no known side effects with consuming maltodextrin.

Blood Draw:
There are possible side effects associated with blood collection. These include pain, small bruises, bleeding, infection, or rarely anemia and fainting.

Unknown risks and discomforts:
The experimental treatments may have side effects that no one knows about yet. The researchers will let

ID: IRB#17-000617 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#17-000617 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 [x]

Provide the following information as appropriate to the study:

ID: IRB#17-000617 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.

- [ ] No payment will be provided
- [x] **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.

Subjects will receive $50 for completion of baseline and week 2 for a compensation up to $100 for the completion of the study in full. Subjects will not be paid for participation in the screening phase of the study.

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

○ Yes ◉ **No**

3.1 **If yes, describe:**

ID: IRB#17-000617 View: NEW 17.1 - HIPAA Authorization

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**.
- [ ] **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.
- [ ] **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**

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.

ID: IRB#17-000617 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:

- [x] **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
- [x] **Referrals (e.g., referrals from non-investigator healthcare providers, snowball sampling, participants referring other participants, etc.)**
- [ ] 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#17-000617 View: NEW 18.2 - Recruitment Methods

This view has been locked by amendment(s)

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 #
Flyer 071017	0.02
Flyer CLEAN 071017	0.01

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.
IRB-approved flyers will also be posted around campus and a separate newspaper advertisement will be run if additional recruitment is necessary.

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 one of the investigators encounters a potential participant in clinical practice, during the course of conducting another study, or in events of daily professional or private life, the investigator will give the participant the information of the study coordinator and if appropriate, provide the potential participant with printed information and/or the informed consent form. The participant will be given time to read the materials and discuss with their friends, family or outside healthcare providers if desired.

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.
Researchers will make clear in conversation that the decision to participate in the study is optional and will not adversely affect any relationship the patient may have with UCLA, another employer, the researcher, or any mutual affiliation the participant may share with the researchers.

ID: IRB#17-000617 View: NEW 19.1 - Eligibility Screening

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

You indicated that eligibility screening will be conducted during the recruitment process (Section 19.1/item 1.0). Please provide the following information.

2.0 ***Will private identifiable information be collected during the screening?**

(●) **Yes** ( ) No

2.1 **If private identifiable information is collected during screening, are there plans to retain data from participants found to be ineligible for the study?**

( ) Yes (●) **No**

2.2 **If private identifiable data will be collected during the screening, indicate your plans for retaining the data.**

- [x] **The data will be retained with identifiers**
- [ ] The data will be retained without identifiers
- [x] **The data will be destroyed**

2.2.1 **If you chose more than one response above, explain.**

For participants who qualify to participate, the information will be retained and become part of their records for contact and payment purposes. For participants who do not qualify, the information will be destroyed.

3.0 **Describe how screening will be performed.**

Out of consideration for the participant's time, and to avoid unnecessary use of research team resources, a telephone screening interview will be done prior to scheduling the participant for a screening visit. During the visit, the informed consent process will be completed prior to the conduct of any further study procedures.

4.0 **Attach screening script(s), if applicable.**

Document Name	Document Version #
Screening Script CLEAN 071017	0.01
Screening Script Tracked 071017	0.02

ID: IRB#17-000617 View: NEW 20.1 - Informed Consent Process

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:

- [x] **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.

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#17-000617 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
- [ ] Over the telephone
- [ ] Other

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

- [ ] 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.**
- [ ] 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.**
Subjects will be allowed as much time as needed.

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

ID: IRB#17-000617 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.
- ☑ **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#17-000617 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.
A translation service will be used if appropriate staff is not available.

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#17-000617 View: NEW 24.0 - Additional Information and/or Attachments

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 #
There are no items to display	

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#17-000617 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#17-000617 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#17-000617 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#17-000617 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#17-000617 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#17-000617 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#17-000617 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#17-000617 View: Display - Method Description

Devices/Diagnostics (including Humanitarian Devices - HUD)

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.

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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

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Expanded Access to Drug, Device or Biologic for Treatment Purposes (aka Compassionate Use, Treatment Use)

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Genetic Analyses/Genotyping

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

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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

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Human Gene Transfer/ Recombinant DNA

Studies involving gene transfer and/or recombinant DNA require approval of the UCLA Institutional Biosafety Committee (IBC) and the NIH Recombinant DNA Advisory Committee (RAC) . 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.

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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).

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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.

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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.

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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

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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

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None of the above

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