UCI Office of Research

Human Research Protection Program
Application for IRB Review (APP)
HRP Version 2017

LEAD RESEARCHER:SAMONTE, SUTTERA ANN

HS#:_____
For IRB Office Use Only

Prior HS#:

TITLE OF THE STUDY: Cross-Linguistic Adjective Ordering Preferences

1. Type of Research

A. The purpose, specific aims or objectives of the research are:

○ Biomedical ◉ Social/ Behavioral/ Educational

B. The research protocol is:

◉ Investigator Authored ○ Industry Authored *Sponsor Master Protocol required*

C. Does this research meet the definition of a clinical trial?

○ Yes ◉ No

D. If currently available, provide the CT.gov registration #: NCT

2. Level of Review

Review the Levels of IRB Review web page for more information. You may also contact the HRP staff at IRB@research.uci.edu or by telephone for assistance.

Select the required level of review for this protocol:

◉ **Exempt Registration** - No more than minimal risk to subject; specific categories:
Select the applicable exempt category(ies):
1. ☐ 2. ☑ 3. ☐ 4. ☐ 5. ☐ 6. ☐

○ **Expedited Review** - No more than minimal risk to subjects; specific categories:
Select the applicable expedited category(ies):
1. ☐ 2. ☐ 3. ☐ 4. ☐ 5. ☐ 6. ☐ 7. ☐

○ **Full Board Review** - greater than minimal risk

Note: If the research is being funded by a component of the Department of Defense (DoD), such as the Air Force or the Office of Naval Research; the DoD requires that independent scientific review and approval occur prior to IRB review regardless of the level of review.

3. Research Unit For This Study

This study will be performed under the auspices of a Department or Division (includes school centers and school-based research units).
Note: The Department Chair's signature will be required prior to IRB review.

A. List the name of the Department or Division: Linguistics

B. List the name of the Department Chair :

First/Middle Name	Last Name	Email Address
LISA	PEARL	lpearl@uci.edu

This study will be performed under the auspices of an Organized Research Unit, Special Research Programs, and Campus Centers
Note: The Director's signature will be required prior to IRB review.

A. List the ORU, Special Research Program or Campus Center:

B. List the name of the Director:

4. Study Funding Indicate funding source(s)

Funding--identify source(s):

- [ ] Grant/Subaward
- [ ] Contract/Subcontract
- [x] Department or campus funds (includes department support, unrestricted funds, start-up funds, personal funds, campus program awards, etc.)
- [ ] Non-cash support from manufacturer/sponsor (e.g., free drug, device, research materials)

  Sponsor Name:
- [ ] Subject/subject's insurance/third party payer
- [ ] No Campus or Extramural funding
- [ ] Undergraduate Research Opportunities Program (UROP)

Conflict of Interest Form(s) 700U:

Is the sponsor or prime sponsor a non-governmental entity (such as a for-profit or non-profit entity)?

○ Yes ○ No

5. Study Team Members

A. Lead Researcher

UCInetID: ssamonte
Employee ID:
Student ID: 34718301
Affiliation: Undergraduate Student

First/Middle Name:	**SUTTERA ANN**
Last Name:	**SAMONTE**
Email Address:	**ssamonte@uci.edu**
Home Department:	

Lead Researcher has an approved exception for PI eligibility and requested an exception to LR eligibility.

B. Faculty Sponsor

First/Middle Name:	
Last Name:	
Email Address:	
Home Department:	

C. Co-Researcher(s)

First/Middle Name	Last Name	Email Address	Affiliation
GREGORY	SCONTRAS	g.scontras@uci.edu	faculty

D. Other Research Personnel

E. Administrative Contacts

6. Single IRB Review/IRB Reliance

UCI promotes and engages in Single IRB Review (sIRB) agreements that allow one IRB review for multi-site research and for collaborative research. The goal is to reduce duplication in review and increase efficiency.

These agreements vary in scope (a single project agreement versus master agreement), in type of research (all types of human research versus limited to industry-authored clinical trials), and nature of the IRB (central IRB such as NCI CIRB, an independent IRB such as Western IRB; or a collaborative IRB model where any one IRB partner to the agreement can be the reviewing IRB such as the UC IRBs).

We recommend that you refer to the Single IRB Review/IRB Reliance web pages for more information or contact our IRB Reliance Unit: irbreliance@uci.edu. **Note:** All UCI human research activities approved through a Single IRB Review process must be registered with UCI IRB and must comply with applicable UCI policies and procedures, regardless of funding or location of performance sites.

IMPORTANT NOTE: For sIRB requests where UCI is asked to serve as the reviewing IRB for more than two non-UC sites, please contact the sIRB team at irbreliance@uci.edu before submitting the IRB Application.

A. Will this protocol be reviewed under a sIRB process?

- ◉ a. No, there is no reliance involved. UCI serves as the IRB of record.
- ○ b. Yes, UCI will be the reviewing IRB. Other sites will rely on UCI. *Appendix R required*
- ○ c. Yes, UCI will rely on another non UCI IRB. *Appendix R required*

B. Identify the sIRB collaboration and the relying institution(s), when applicable.

○ **Children's Hospital Orange County (CHOC), MemorialCare Health System (MHS), and UC Irvine (UCI) - CMU IRB Reliance**

The CMU IRB Reliance is for collaborative research conducted across CHOC, MHS, UCI and their associated sites.

1. Participating Site(s):

☐ CHOC ☐ MHS

2. List Reviewing IRB (if not UCI):

☐ CHOC ☐ MHS

○ **National Cancer Institute Central Institutional Review Board (NCI CIRB)**

The NCI Adult CIRB – Late Phase Emphasis reviews Phase III Cooperative Group studies from ACOSOG, GOG, NSABP, RTOG, and SWOG.

○ **University of California (UC) IRB Reliance**

The UC IRB Reliance is for collaborative research conducted across UC campuses

1. Participating Site(s):

☐ Berkeley ☐ Davis ☐ Los Angeles ☐ Merced

☐ Riverside ☐ San Diego ☐ San Francisco ☐ Santa Barbara

☐ Santa Cruz ☐ Lawrence Berkeley National Lab

2. List Reviewing IRB (if not UCI):

☐ Berkeley ☐ Davis ☐ Los Angeles ☐ Merced

☐ Riverside ☐ San Diego ☐ San Francisco ☐ Santa Barbara

☐ Santa Cruz ☐ Lawrence Berkeley National Lab

○ **Independent IRBs**

UCI has established IRB Agreements with several independent IRBs for industry-authored, multi-site clinical trials and clinical research where the sponsor or Clinical Research Organization has chosen the independent IRB as the IRB of Record for the study.

Indicate the Reviewing IRB:

☐ Chesapeake IRB

☐ Quorum IRB

☐ Schulman IRB

☐ Western (WIRB)/Copernicus Group IRB (CGIRB)

Single Study IRB Agreements

Where a protocol specific IRB Authorization Agreement will need to be established with the another entity:

Specify the IRB of Record (if not UCI):

Provide IRB contact information for other entity:

Note: UCI may agree to rely on a non-UCI IRB under the following circumstances:

1. UCI LR is collaborating with non-UC investigator
2. The human research activities conducted by the UCI study team constitute minimal risk research (expedited level)
3. No UCI study team member has a disclosable financial interest that would require review by the UCI Conflict of Interest Oversight Committee (COIOC). UCI may establish an IRB Authorization Agreement with the Reviewing IRB's Institution

7. Scientific/Scholarly Review

Investigator-authored research involving greater than minimal risk to subjects (full board review) requires scientific/scholarly merit prior to IRB review - with few exceptions. The following options identifies the scientific merit process for the proposed research and the order of IRB review. Researchers should work with their Departments and the applicable committee (e.g., PRMC) to coordinate the review of their projects, as necessary.

Indicate the scientific/scholarly review of the research described in this IRB application.

Minimal Risk Research: Department/Division/Institute Review
The proposed research qualifies as exempt or expedited research. The Department Chair, Division Chief, or Institute Director provides assurance that the research uses procedures consistent with sound research design, the study design can be reasonably expected to answer the proposed question, and the importance of the knowledge expected to result from the research is known.

Investigator Initiated Cancer Research **- PRMC Review Required**
Cancer research includes research involving prevention, treatment and survivorship or supporting care. This includes research that involves a social behavioral or educational hypothesis. Chao Family Comprehensive Cancer Center Protocol Review and Monitoring Committee (PRMC) review is required prior to IRB review for investigator-initiated research that has not received prior peer review. This includes both greater than minimal risk and minimal risk research. If the study involves a cancer focus, researchers should confirm with the PRMC whether their review is required prior to initiation of research. This includes both greater than minimal risk and minimal risk research.

Greater than Minimal Risk ***Sponsor Initiated Biomedical Research*** **- Received Peer Review**
The proposed research is sponsor initiated. The sponsor is an industry sponsor, a federal sponsor, or a non-profit, private sponsor. It is assumed that scientific merit has been conducted. Available peer review comments may be requested by the IRB for consideration.

○ **Greater than Minimal Risk *Investigator Initiated Biomedical Research* - IRB / BERD Review Required**
The proposed research is investigator initiated and has not been peer review. The UCI IRB will review the research for scientific merit in conjunction with the expertise of the Biostatistics, Epidemiology and Research design (BERD) unit of the Institute for Clinical and Translational Science (ICTS). The UCI IRB staff will coordinate the review process.

○ **Greater than Minimal Risk *Investigator Initiated Social Behavioral Educational Research* - Department / Division / Institute Review**
The proposed research is investigator initiated and involves a social, behavioral, or educational hypothesis. The research does not have a cancer focus. The Department Chair, Division Chief, or Institute Director assures that the research uses procedures consistent with sound research design, the study design can be reasonably expected to answer the proposed question, and the importance of the knowledge expected to result from the research is known.

Note: If the research is being funded by a component of the Department of Defense (DoD), such as the Air Force or the Office of Naval Research; the DoD requires that independent scientific review and approval occur prior to IRB review regardless of the level of review.

8. Research Performance Sites

A. Check whether research will take place at a ◉ **Single Site** or ○ **Multiple Sites** .
Single Site refers to research conducted at UCI only - and may include multiple UCI affiliated sites (e.g., UCIMC, Gottschalk, Beckman Laser, etc.).
Multiple Sites refers to research occurring at UCI and another non-UCI entity engaged in research (e.g., UCLA, Nursing Home, School, etc.).

B. Check all sites where UCI investigator(s) will conduct research activities (e.g., recruitment, informed consent, and research procedures including accessing identifiable, private information about participants).

- ☑ UCI Main Campus
- ☐ UCIMC and/or UCIMC satellite clinics (i.e., Anaheim, Santa Ana and Costa Mesa)
- ☐ Beckman Laser Institute and Medical Clinic
- ☐ Institute for Clinical and Translational Science (ICTS) (UCI Campus or Medical Center)
- ☐ Gottschalk Medical Plaza
- ☐ Other UCI site(s), including UCI-leased space (identify):
- ☐ Other Non-UCI Sites and Locations (i.e., not UCI, UCIMC, or UCI owned/leased space - Identify):
  Appendix A Required
- ☐ Public Locations (e.g. coffee house, public park, library) - Identify:

9. Subject Populations/Data Sources

- ☐ Use of identifiable or coded data, specimens, records, charts
- ☐ Use of California State Death Data Files Containing Personal Identifying Information

- [x] Adults Competent to Provide Informed Consent
- [ ] Children *Appendix D Required*
- [ ] Pregnant Women/Neonates *Appendix B Required*
- [ ] Prisoners *Appendix C Required*
- [ ] Adults who are cognitively impaired *Appendix E Required*
- [ ] Adults who are medically impaired *Appendix E Required*
- [ ] Subjects who are unable to communicate in English
- [ ] UCI students/staff/faculty
- [ ] UCI Inpatients or Outpatients (Receiving Diagnosis/Treatment/Surgery)

10. Research Procedures Involved in the Study

The procedures in grey cannot be reviewed as Exempt research. Please go back and change Level of Review to Expedited or Full Committee in order to select them.

- [ ] Analysis of Existing Identifiable or Coded Data, Specimens, Records, Charts, and Datasets
- [x] Surveys/Questionnaires/Interviews/Oral Histories
- [ ] Audio, Video, Digital or Image Recording and/or Photography for Collection of Research Data
- [ ] Behavioral Experiments (e.g., Cognition, Perception, Motivation, Communication, Social Behavior)
- [ ] Studies Involving Incomplete Disclosure or Deception *Appendix G Required*
- [ ] Observation of Public Behavior
- [ ] Evaluation of Programs or Services
- [ ] International Research *Appendix H Required*
- [ ] Field Work Studies *Appendix I Required*
- [ ] Collection of Blood Samples (Venipuncture)
- [ ] Collection of Other Samples/Specimens (e.g.,tissue, saliva, urine)
- [ ] Genetic Analysis *Appendix N Required*
- [ ] Repository - Identifiable or Coded Data and/or Biological Specimens for Future Research *Appendix M Required*
- [ ] Clinical Investigation focusing on an Approved or Investigational Drug *Appendix J Required*

i. Indicate the phase of the research, if applicable:

a. ☐ Phase I
b. ☐ Phase II
c. ☐ Phase III
d. ☐ Phase IV
e. ☐ Not Applicable

ii. If the study involves an Investigational New Drug (IND) application, specify the holder of the IND:

a. ☐ Industry Sponsor
b. ☐ UCI Investigator/Sponsor (Reminder: the protocol must meet GCP Guidelines)
c. ☐ UC/UCI Institution
d. ☐ Non-UC/UCI Investigator
e. ☐ Other (e.g., NIH, GOG, CTEP):

f. ☐ Industry Sponsor
g. ☐ UCI Investigator/Sponsor (Reminder: the protocol must meet GCP Guidelines)
h. ☐ UC/UCI Institution
i. ☐ Non-UC/UCI Investigator
j. ☐ Other (e.g., NIH, GOG, CTEP):

k. ☐ Industry Sponsor
l. ☐ UCI Investigator/Sponsor (Reminder: the protocol must meet GCP Guidelines)
m. ☐ UC/UCI Institution
n. ☐ Non-UC/UCI Investigator
o. ☐ Other (e.g., NIH, GOG, CTEP):

p. ☐ Industry Sponsor
q. ☐ UCI Investigator/Sponsor (Reminder: the protocol must meet GCP Guidelines)
r. ☐ UC/UCI Institution
s. ☐ Non-UC/UCI Investigator
t. ☐ Other (e.g., NIH, GOG, CTEP):

u. ☐ Industry Sponsor
v. ☐ UCI Investigator/Sponsor (Reminder: the protocol must meet GCP Guidelines)
w. ☐ UC/UCI Institution
x. ☐ Non-UC/UCI Investigator
y. ☐ Other (e.g., NIH, GOG, CTEP):

z. ☐ Industry Sponsor
{. ☐ UCI Investigator/Sponsor (Reminder: the protocol must meet GCP Guidelines)
|. ☐ UC/UCI Institution
}. ☐ Non-UC/UCI Investigator
~. ☐ Other (e.g., NIH, GOG, CTEP):

- ☐ Industry Sponsor
- ☐ UCI Investigator/Sponsor (Reminder: the protocol must meet GCP Guidelines)
- ☐ UC/UCI Institution
- ☐ Non-UC/UCI Investigator
- ☐ Other (e.g., NIH, GOG, CTEP):

☐ Clinical Investigation focusing on an Investigational Device *Appendix K Required*

i. If the study involves an Investigational Drug Exemption(IDE) application, specify the holder of the IDE:

a. ☐ Industry Sponsor
b. ☐ UCI Investigator/Sponsor (Reminder: the protocol must meet GCP Guidelines)
c. ☐ UC/UCI Institution
d. ☐ Non-UC/UCI Investigator
e. ☐ Other (e.g., NIH, GOG, CTEP):

f. ☐ Industry Sponsor
g. ☐ UCI Investigator/Sponsor (Reminder: the protocol must meet GCP Guidelines)
h. ☐ UC/UCI Institution
i. ☐ Non-UC/UCI Investigator
j. ☐ Other (e.g., NIH, GOG, CTEP):

k. ☐ Industry Sponsor
l. ☐ UCI Investigator/Sponsor (Reminder: the protocol must meet GCP Guidelines)
m. ☐ UC/UCI Institution
n. ☐ Non-UC/UCI Investigator
o. ☐ Other (e.g., NIH, GOG, CTEP):

p. ☐ Industry Sponsor
q. ☐ UCI Investigator/Sponsor (Reminder: the protocol must meet GCP Guidelines)
r. ☐ UC/UCI Institution
s. ☐ Non-UC/UCI Investigator
t. ☐ Other (e.g., NIH, GOG, CTEP):

u. ☐ Industry Sponsor
v. ☐ UCI Investigator/Sponsor (Reminder: the protocol must meet GCP Guidelines)
w. ☐ UC/UCI Institution

x. ☐ Non-UC/UCI Investigator
y. ☐ Other (e.g., NIH, GOG, CTEP):
z. ☐ Industry Sponsor
{. ☐ UCI Investigator/Sponsor
(Reminder: the protocol must meet GCP Guidelines)
|. ☐ UC/UCI Institution
}. ☐ Non-UC/UCI Investigator
~. ☐ Other (e.g., NIH, GOG, CTEP):

- ☐ Experimental Surgical Procedures
- ☐ Use of Placebo, Placebo Washout or Sham Procedure *Appendix L Required*
- ☐ Use of Radiopharmaceuticals or Radiation-Producing Machines (e.g., CT scan, DEXA, PET, Radiation Therapy, SPECT, Scintigraphy, and X-Ray)
- ☐ Other Imaging (MRI, fMRI, Ultrasound, Optical)
- ☐ Other Non-invasive Physical Measurements (e.g., ECG, EEG, moderate exercise, muscular strength testing, body composition assessment)

11. Informed Consent Process

- ☐ Signed Informed Consent *Consent Form required*
- ☐ Signed Parental Permission *Consent Form required*
- ☐ Signed Child Assent *Assent Form required*
- ☐ Signed Translated Consent Form for non-English speakers/readers
- ☐ Use of Short Form Consent Process for non-English speakers/readers *Appendix Q Required*
- ☐ Use of Surrogate Consent Process *Appendix E Required*
- ☑ Waiver of Signed Informed Consent (oral consent obtained) *Appendix P Required*
- ☐ Waiver of Signed Parental Permission (oral permission) *Appendix P Required*
- ☐ Waiver of Signed Assent (oral child assent) *Appendix D Required*
- ☐ Waiver or Alteration of Informed Consent (no consent or altered consent process) *Appendix O Required*
- ☐ Waiver of Informed Parental Permission (no permission process) *Appendix O Required*
- ☐ Waiver of Assent (no child assent process) *Appendix D Required*

12. HIPAA Research Authorization

HIPAA is the acronym for the Health Insurance Portability and Accountability Act of 1996. The HIPAA Privacy Rule establishes national standards to protect individuals' medical records and other personal health information and applies to health plans, health care providers and others that conduct health care transactions electronically. The Rule requires appropriate safeguards to protect the privacy of personal health information, and sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization. The Rule also gives patients rights over their health information, including rights to examine and obtain a copy of their health records, and to request corrections. Under the HIPAA Privacy Rule, Protected Health Information (PHI) refers to individually identifiable health information that can be linked to a particular person. If the research involves accessing or collecting PHI, or the research will result in new health information which will be added to a patient's medical record, the research is accessing, using or creating PHI and is subject to HIPAA Privacy Rule provisions.

Under the HIPAA Privacy Rule, PHI refers to individually identifiable health information. Individually identifiable health information is that which can be linked to a particular person.

If the research involves accessing or collecting PHI, or the study will result in new health information which will be added to the subjects medical record, the research is accessing, using or creating PHI and is subject to HIPAA Privacy Rule provisions.

List of 18 PHI Identifiers

- Names
- Social Security Numbers
- Dates*
- Medical record numbers
- Address
- Health plan numbers
- Phone numbers
- Fax numbers
- Email address
- Account numbers
- License/Certificate numbers
- Vehicle ID numbers
- Device identifiers/Serial numbers
- Web URLs
- IP address numbers
- Biometric identifiers
- Facial Photos/Images
- Any other unique identifier

* All elements (except years) of dates related to an individual (including birth date, admission date, discharge date, date of death and exact age if over 89)

A. Does this study involve accessing, collecting or creating PHI?

○ Yes ◉ No

B. If YES above, HIPAA regulations apply to this research study. Investigators are required to obtain a signed HIPAA Research Authorization from each subject, request a waiver of HIPAA Research Authorization from the IRB, which serves as the HIPAA Privacy Board, or use a Limited Data Set# which does not call for signed authorization, but requires that the investigator sign a Data Use Agreement.

Check all of the following boxes that apply:

☐ Subjects will sign a UC HIPAA Research Authorization for Release of PHI for Research Purposes. *HIPAA Authorization Form required*

☐ A waiver of HIPAA Research Authorization is requested *Appendix T required*

☐ A de-identified data set is requested.

The de-identified data set does not include any of the 18 identifiers listed above for the subject or the subject's relatives, employer or household members.

☐ A Limited Data Set will be obtained. A Data Use Agreement will be signed.
Specify the entity that will provide the PHI for the limited data set. If the limited data set will be obtained from a non-UC entity, the Data Use Agreement must be negotiated and signed by a UCI Sponsored Projects Officer. If the data set will be obtained from UCI or from another UC, the Data Use Agreement must be signed by the UCI SOM Research Compliance Officer.

A limited data set may include only 1) five digit zip code; 2) dates of birth and death; 3) dates of admission and discharge; 4) a geographic subdivision other than street address. The limited data set may not include any other PHI listed above for the subject, relatives, employer, or household members.

13. Data and Safety Monitoring

In keeping with NIH requirements and with federal regulations that require that IRBs assure that the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects, UCI IRB requires that all clinical investigations involving greater than minimal risk to subjects develop a data and safety monitoring plan to assure the safety and welfare of the research subjects.

Does this study require a DSM plan?

◉ No
○ Yes *Appendix S required*

14. Potentially Hazardous Materials

If any of the following materials are involved in this research please check below:

Note: IBC Review and/or Radiation Safety Committee Review may be required

☑ N/A
☐ Carcinogens (list here):
☐ Etiologic agents or infectious agents(list here):
☐ Human/primate blood, tissue, fluids or primary cells(list here):
☐ Radioactive substances (list here):

- ☐ Radiation-producing machines (list here):
- ☐ Recombinant DNA (including human gene transfer, a.k.a. "gene therapy")(list here):
- ☐ Regulated toxic chemicals (list here):
- ☐ Toxins (list here):
- ☐ Controlled Substance (list here):

15. Other UCI Committee Reviews

Research involving human subjects sometimes requires the approval or authorization of Other Reviews Required by UCI (e.g., School of Medicine Review Committees). Check all applicable regulatory or institutional reviews that are required for this study. **The following list includes those ancillary regulatory committees whose review may impact final IRB approval. For a list of all ancillary committees, their requirements and how they relate to the IRB review process, refer to the HRP webpage.**

- ☑ N/A
- ☐ Human Stem Cell Research Oversight Committee (HSCRO)
- ☐ Institutional Biosafety Committee (IBC)
- ☐ Radiation Safety Committee (RSC)

16. Additional IRB Documentation to be Completed and Uploaded

If required documentation (denoted in bold below) is not provided the submission is incomplete and you will not be able to submit the IRB Application. Please review the below list of required documentation carefully. Be sure to upload each document as required. If changes are needed, go back to the sub-section to revise your selections.

All UCI templates are available on the Applications & Forms page, subsection "Human Research Protections."

Protocol Narrative **(Based on Type of Research and Level of Review)**:

1. Biomedical Exempt
2. Biomedical Expedited and Full Committee
3. **Social / Behavioral / Educational Exempt**
4. Social / Behavioral / Educational Expedited and Full Committee

Other Documents that May be Required (Based on Research):

5. Consent Form (signed consent or parental permission)
6. Assent Form (child agreement)
7. HIPAA Research Authorization Form
8. Sponsor Master Protocol

IRB Appendices that May be Required (Based on Research):

Note: If UCI IRB is the Reviewing IRB a list of Required Appendices will be provided. The list is largely based on your responses in the Subject Populations/Data Sources and Research Procedures sections.

- Appendix A - UCI Research Performed at Non-UCI Sites and Locations
- Appendix B - Vulnerable Populations: Pregnant Women, Human Fetuses, or Neonates
- Appendix C - Vulnerable Populations: Prisoners
- Appendix D - Vulnerable Populations: Children
- Appendix E - Cognitively Impaired/Medically Incapacitated Subjects and Use of Surrogate Consent
- Appendix G - Use of Deception/Incomplete Disclosure
- Appendix H - International Research
- Appendix I - Ethnographic Research/Field Work
- Appendix J - Use of FDA-Approved Drugs and Investigational Drugs or Biological Products in Clinical Investigations
- Appendix K - Use of FDA Approved or Cleared Devices and Investigational Devices in Clinical Research Studies
- Appendix L - Justification for Use of a Placebo or Sham Procedure, or Placebo Washout Period
- Appendix M - Storage of Data and/or Specimens for Future Research
- Appendix N - Collection of Genetic Specimens and Genetic Testing Studies
- Appendix O - Request for a Waiver of Informed Consent
- Appendix P - Request for a Waiver of Written(Signed) Consent
- Appendix Q - Request for Use of a Short Form Consent Process
- Appendix R - Relying Principal Investigator Study Worksheet ,
- Appendix S - Description of Data Safety Monitoring Plan (DSMP)
- Appendix T - Request for a Waiver or Partial Waiver of HIPAA Authorization

Other Documents as applicable:

- Study Information Sheet (oral or web-based consent)
- Recruitment Materials
- Investigator's Brochure
- Letter of Permission (Non-UCI location)

If you have any questions, please call the Human Research Protections staff at:

- For Biomedical / Clinical Research: (949) 824-6068 or (949) 824-2125 or (949) 824-0665
- For Social / Behavioral / Educational Research: (949) 824-6662
- Or send an e-mail to irb@research.uci.edu

Departmental or Organized Research Unit (ORU) Approval

The Department Chair's signature is required if the study will be performed under the auspices of a Department (includes campus centers and school-based research units). If the Department Chair is a member of the research team on this application (including Faculty Sponsor), or if the Department Chair has a disclosable conflict of interest with this research, approval must be obtained from the next highest level of administrative authority [i.e., School Dean, Executive Vice Chancellor (the Vice Chancellor for Research signs on behalf of the EVC)].
The ORU Director's signature is required if the study will be performed under the auspices of an ORU. If the ORU Director is a member of the research team on this application (including Faculty Sponsor), approval must be obtained from the Vice Chancellor for Research or designee.

Department or ORU Assurance Statement:

By signing below, I hereby confirm that:

1. I have no disclosable conflict of interest related to this research.
2. The research is appropriate in design (i.e., the research uses procedures consistent with sound research design, the study design can be reasonably expected to answer the proposed question, and the importance of the knowledge expected to result from the research is known).
3. The Lead Researcher (and Faculty Sponsor) is competent to perform (and supervise) the study.
4. All study team members are aware of their responsibility to disclose to the COIOC any disclosable financial interests in the research.
5. There are adequate resources and funds available to support the performance of this research.

Typed Name of UCI Department Chair/ORU Director	Signature of UCI Department Chair/ORU Director	Date signed
Lisa S. Pearl		10/5/17

INVESTIGATOR'S ASSURANCE STATEMENT
University of California, Irvine
Institutional Review Board

Study Title: Cross-Linguistic Adjective Ordering Preferences

As Lead Researcher, I have ultimate responsibility for the performance of this study, the protection of the rights and welfare of the human subjects, and strict adherence by all co-investigators and research personnel to all Institutional Review Board (IRB) requirements, federal regulations, and state statutes for research involving human subjects.

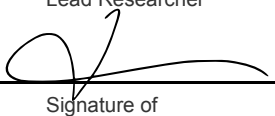
I hereby assure the following:

1. The information provided in this application is accurate to the best of my knowledge.
2. All named individuals on this project have read and understand the procedures outlined in the protocol and their role on the study.
3. All named individuals on this project have completed the *required* Educational research tutorials and have been made aware of the "Common Rule" (45 CFR Part 46), applicable Food and Drug Administration (FDA) regulations (21 CFR Parts 50, 56, 312 and 812), have read the Belmont Report, and UCI's Federalwide Assurance (FWA) that are available on the Human Research Protections Program (HRP) website.
4. All experiments and procedures involving human subjects will be performed under my supervision or that of another qualified professional listed on this protocol.
5. I understand that, should I use the project described in this application as a basis for a proposal for funding (either intramural or extramural), it is my responsibility to ensure that the description of human subjects activities in the funding proposal(s) is identical in principle to that contained in this application. I will submit modifications and/or changes to the IRB as necessary to ensure these are identical.

I and all co-investigators and research personnel agree to comply with all applicable requirements for the protection of human subjects in research including, but not limited to, the following:

1. Obtaining the legally effective informed consent of all human subjects or their legally authorized representatives (unless waived) and using only the currently approved, stamped consent form (if applicable).
2. Per federal regulations, once a human research study has received IRB approval, any subsequent changes to the study must be reviewed and approved by the IRB prior to implementation except when necessary to avoid an immediate, apparent hazard to a subject. See Reporting of Unanticipated Problems.
3. Reporting any unanticipated problems involving risk to subjects or others, including protocol violations per UCI IRB policy. In addition, HIPAA privacy violationsnmust be PROMPTLY disclosed to the UCI Privacy Officer. There are time requirements for reporting these breaches of confidentiality, which, if not met, may result in monetary damages to the researcher and the institution.
4. Responding appropriately to subjects' complaints or requests for information about the study; and reporting to the IRB any subject complaints that are not resolvable by the study team.
5. Promptly providing the IRB with any information requested relative to the project.
6. Assuring the appropriate administration and control of investigational test articles (i.e., investigational drugs, biologics or devices) by a qualified investigator or other appropriate individual or entity (e.g., UCIMC pharmacy), and assuring use and maintenance of an *Investigational Drug/Biologic Accountability Log or Device Accountability Log*.
7. Registering applicable clinical trials with clinicaltrials.gov. For more information about this topic, visit the ClinicalTrials.gov web page or the HRP webpage. The consequences of not meeting the registration and reporting requirements include monetary damages to the researcher and the institution.
8. Obtaining continuing review prior to study expiration (I understand if I fail to apply for continuing review, approval for the study will automatically expire, and all human research activities must cease until IRB approval is obtained).
9. Promptly and completely complying with an IRB decision to suspend or terminate its approval for some or all research activities.
10. Submitting to a routine review of human subject research records. The Compliance & Privacy Office at UCI Health performs ongoing routine reviews of open biomedical research protocols, in an effort to ensure in part that human subject research activities are conducted in accordance with regulations, laws and institutional policies regarding the protection of human subjects. In addition, the HRP unit of the Office of Research has developed the Education Quality and Improvement Program (EQUIP). Through EQUIP, HRP staff conduct periodic quality improvement monitoring and educational outreach.
11. Filing a final report with UCI HRP at the conclusion of this project.

SAMONTE, SUTTERA ANN

Typed Name of Lead Researcher	Signature of Lead Researcher	Date
Gregory Scontras		**10/5/2017**

Typed Name of Faculty Sponsor (if a Faculty Sponsor is required)	Signature of Faculty Sponsor	Date

Disclosure of Investigators' Financial Interest
University of California, Irvine
Institutional Review Board

Study Title: Cross-Linguistic Adjective Ordering Preferences

In order to inform research subjects of circumstances that may affect their decision to participate in this study, all researchers are required to disclose their financial interests with outside institutions.

The Lead Researcher of the protocol must ask the following question of all study team members:

- **"Does the proposed study evaluate a University invention in which you have an ownership interest?"**
- **"Do you, your spouse, and dependent children together have any disclosable financial interests (i) that would reasonably appear to be affected by the research; or (ii) in entities whose financial interests would reasonably appear to be affected by the research?"**

Disclosable financial interests are:

- Ownership interest, stock, stock options, or other financial interest related to the research, unless it meets all four tests:
  - Less than $10,000 when aggregated for the immediate family and
  - Publicly traded on a stock exchange and
  - Value will not be affected by the outcome of the research and
  - Less than 5% interest in any one single entity.
- Compensation related to the research, including salary, consultant payments, honoraria, royalty payments, dividends, loans, or any other payments or consideration with value, including payments made to the University Health Sciences Compensation Plan, unless it meets both of the following tests:
  - Less than $10,000 in the past year when aggregated for the immediate family and the
  - Amount will not be affected by the outcome of the research.
- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
- Board or executive relationship (e.g., director, officer, partner, or trustee) related to the research, regardless of compensation.

A member of the study team who answers in the affirmative to either question must be listed in the box below. An e-mail will be sent to the study team members listed below to obtain additional information regarding the specific financial interest(s). IRB approval cannot be granted until all disclosures are reviewed.

Name	Ownership Interest in University Invention?	Any Disclosable Financial Interest?

Lead Researcher Certification:
I certify that all members of the study team have answered the financial interest questions and only the individual(s) listed in the box above have a disclosable financial interest.

Signature of Lead Researcher:_____

Date Signed:_____

The following documents as named have been successfully uploaded to IRB Application #11774:

File Description
Survey Information Sheet
Protocol Narrative
Study Information Sheet