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:**
Physiology of emotional reactivity

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

2.0 ***Working or Lay Title:**
EGG/COVID and Emotionality

3.0 **Principal Investigator:**

3.1 ***Name:** BRIDGET CALLAGHAN
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.
Ph.D.

3.2 **UCLA Title:**

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

- ○ Yes
- ◉ **No**
- ○ Not Applicable

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

○ Yes ◉ **No**

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

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

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

Document Name	Document Version #
There are no items to display	

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

Emily Towner

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

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

	Name	Department	Role	Other Role (if applicable)	Will Obtain Consent?	Manage device accountability?	Access to personally identifiable info?	Access to code key?
View	Emily Towner	PSYCHOLOGY	Research Assistant Study Coordinator		yes	Not Applicable	Yes	Yes

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:** BRIDGET CALLAGHAN
***Please type the Degree(s):** Ph.D.

1.2 **Principal Investigator's UCLA Department:** PSYCHOLOGY

1.3 ***Protocol's UCLA Home Department:** PSYCHOLOGY

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.
View	Research Volunteers	There will be a range of research volunteers who will be involved in this research study. The volunteers will recruit participants, obtain consent, run the research protocol, have access to personally identifiable information, and have access to the code key.

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

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

Check all that apply:

- [x] **CITI Training**
- [ ] UC HIPAA Training
- [ ] Other

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

3.0 ***Will any of the study procedures or analyses be contracted to a consultant or an organization?**

○ Yes ◉ **No**

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

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.*

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

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

○ Yes
○ No

ID: IRB#20-000295 View: NEW 1.2 - Conflict of Interest Information

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

Conflict of Interest Information

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

○ Yes ◉ **No**

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

Document Name	Document Version #
There are no items to display	

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

○ Yes ◉ **No**

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

Document Name	Document Version #
There are no items to display	

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

○ Yes ◉ **No**

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

Document Name	Document Version #
There are no items to display	

ID: IRB#20-000295 View: NEW 1.3 - Study Locations

This view has been locked by amendment(s)

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:

- ☑ **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
- ☐ Timely e-mail communications
- ☐ Postings on the study website
- ☐ Other

2.1.1.1 If you chose "other", describe.

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

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

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

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:

- ☑ **UCLA investigator**

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

3.1 If other, specify.

4.0 Review For and Reliance Upon External IRBs.

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

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

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

( ) Yes (•) **No**

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

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

( ) Yes (•) **No**

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

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

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

( ) Yes (•) **No**

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

Check all that apply.

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

7.1.1 If you checked "other", describe.

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

Document Name	Document Version #
There are no items to display	

ID: IRB#20-000295 View: NEW 2.2 - Lay Summary and Keywords

This view has been locked by amendment(s)

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 study will explore the relationship between somatic symptoms and emotions in a two-part study.

Part 1

Part 1 will be an online study that will explore the relationship between emotions and somatic symptamology in the wake of the COVID-19 pandemic, while exploring individual differences in social, environmental, personality, and lifestyle factors which may mitigate or exacerbate the negative psychological impact of this stressor.

The specific aims of this study are to (1) establish a relationship between psychological stress and somatic symptoms as assessed by our newly developed Somatic Symptoms of Negative Affect (somna) questionnaire, (2) investigate the individual differences that might influence the somatic and psychological response to stress (such as early life stress, social support, media consumption, diet and exercise, lifestyle habits, trait variables, etc.), and (3) examine how specific somatic symptoms in the context of stress may relate to mental health.

Part 2

Part 2 will be an in person study that will explore the relationship between gastrointestinal activity and emotions utilizing electrogastrography. The specific aims of this study are to (1) establish a relationship between emotionally arousing stimuli and the EGG response, (2) investigate the individual differences that might influence the EGG response to stress (such as early life stress, current stress, trait variables, etc.), (3) examine how the EGG response sits with other physiological indices (such as heart rate and sweat response), and (4) explore the ways in which physical sensations are associated with emotions and physiological responses.

We will recruit N = 150 adult participants.

For part 1 participants will complete a range of questionnaires assessing social and emotional functioning, physical health symptoms, early life adversity, physical health, and a range of questionnaires assessing the impact of COVID-19.

For part 2, participants will return for an in-person session in the lab in which they will watch a series of sad, scary, and neutral movies while electrophysiology recordings are made. Then they will complete a range of questionnaires assessing social and emotional functioning, physical health symptoms, early life adversity, and physical health assessments.

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.**

egg, stress, emotions, physiology

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#20-000295 View: NEW 2.3 - Methods/Procedures - Descriptors

This view has been locked by amendment(s)

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
- ☐ 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)
- ☐ 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#20-000295 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#20-000295 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.**

- ☑ **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#20-000295 View: NEW 8.8 - Audio, Visual or Digital Recordings

This view has been locked by amendment(s)

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

Audio, Visual or Digital Recordings

You indicated that this study includes recordings (audio or visual) (section 2.3/item 1.0). Please provide the following information.

1.0 ***Who will transcribe the research tapes/recordings?**

Check as many as apply:

- [x] **Members of the research team**
- [ ] Persons outside the research team

2.0 ***Is the use of recordings an optional part of the research?**

(•) **Yes** ( ) No

3.0 ***Will individual study participants be able to review, edit, and erase the tapes/recordings of their research participation?**

(•) **Yes** ( ) No

3.1 **If no, provide an ethical and scientific justification for NOT allowing study participants to review, edit, and erase the tapes of their research participation.**

4.0 **Transcription of Research Tapes/Recordings**

4.1 ***Type of media (Check as many as apply):**

- [x] **CD ROM**
- [ ] DVD
- [x] **Digital Files**
- [ ] VHS tape
- [ ] Cassette or microcassette
- [ ] Handwritten files
- [ ] Other

4.2 ***Method of transmission (Check as many as apply):**

- [ ] Courier or mail with delivery confirmation
- [ ] Posted to a secure website
- [ ] Email
- [ ] Other
- [x] **Not Applicable**

4.3 ***Transcription Service (Check as many as apply):**

- [ ] Transcription service secures tapes in a secure locked area
- [ ] Transcription(s) sign confidentiality agreements
- [ ] Transmission of voice files and text files is encrypted and password protected
- [ ] Other
- [x] **Not Applicable**

4.3.1 **If you selected "other" for any/all of the above items, describe.**

ID: IRB#20-000295 View: NEW 9.2 - Information about Study Data

This view has been locked by amendment(s)

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
- [ ] 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
- [x] **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)
- [ ] Postal Address
- [x] **Phone Numbers**
- [ ] Fax Numbers
- [x] **E-Mail Address**

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

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

5.0 ***Select all that apply:**

- [x] **The data and/or specimens will be directly labeled with personal identifying information when acquired by the investigator for this research**
- [x] **The data and/or specimens will be labeled with a code that the research team can link to personal identifying information when acquired by the investigator for this research**
- [ ] The data and/or specimens will not be labeled with any personal identifying information, nor with a code that the research team can link to personal identifying information when acquired by the investigator for this research
- [ ] The data are restricted use data (A term used in Social-Behavioral research. See guidance on the right.)

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

Check all that apply:

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

5.1.1 **If Other, specify:**

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).**

The research (data collection and analysis) will be conducted in private settings (the research lab in Pritzker Hall). Only research staff trained or training in the study protocol will be present in the room during the conduct of the research procedures. Video coding will be conducted in the lab and in research assistants' homes. Research assistants agree to code the data in a private setting in a private room.

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 data collected in the study (questionnaires, screening forms, computer games, physiological data) use a unique participant code/identifier (ID) instead of using personally identifying information (e.g., names or emails). Participants are assigned two codes at the start of the study, a primary, and secondary code. Their codes are paired with their name only on a password-protected encrypted ID database, locked in a secure location in the lab, accessible only by key study personnel for the purposes of research (including future contact of research participants).

Video recordings will be stored on a secure server (Box) in a separate folder to deidentified data, labeled with the secondary code. The videos will be coded by trained research assistants in a private setting as described in section 1.0. Deidentified data are stored on a secure server using the participant's primary code and on an external version of UCLA's REDCap. Hard copies of deidentified data are stored in a locked filing cabinet in the locked lab. Video recordings are also stored on two external encrypted hard drives and CD's using the participant's primary code. These hard copies are also locked in a secure location in the lab.

With participant consent/assent, the principal investigator will share only deidentified data from this study publicly with other researchers. This will allow other scientists to check our work. It will also allow our data to be easily pooled across labs, in order to be reused for novel purposes thus, increasing the utility of our research.

Data from this study that are completely deidentified will be publicly shared (e.g., Open Science Framework) with other researchers. This practice enables other scientists to check our work to verify our findings, as well as use these data to answer questions of their own (e.g., the data can be pooled across multiple labs to answer novel research questions, or can be used for novel purposes such as validating questionnaires etc.). The practice of 'open science' is becoming necessary for publication in many journals, and facilitates scientific discovery and transparency.

This study does not collect information on suicidal ideation or intent for which State or Federal Law requires ethical action.

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
- [x] **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**

All data collected in the study (questionnaires, screening forms, computer games, physiological data) use unique participant codes instead of using personally identifying information (e.g., names or addresses). Participants are assigned two codes at the start of the study by a trained research assistant, a primary, and secondary code. Their codes are paired with their name only on a password-protected encrypted ID database, locked in a secure location in the lab, accessible only by key study personnel for the purposes of research (including future contact of research participants).

Deidentified data are stored on a secure server using the participant's primary code. Video recordings are stored on a secure server in a separate folder to deidentified data, using the participant's secondary code. Video recordings are also stored on two external encrypted hard drives and CD's using the participant's primary code. These hard copies are also locked in a secure location in the lab.

Contact information is labeled with participant names, and not with participant codes. The documents with participant names are kept in a separate location from the deidentified data on an encrypted server.

With participant consent the principal investigator will share only deidentified data from this study publicly with other researchers. This will allow other scientists to check our work. It will also allow our data to be easily pooled across labs, in order to be reused for novel purposes thus, increasing the utility of our research.

Personally identifying information (faces and voices) will only be retained in video recordings, all other data is deidentified and the codes are maintained on a locked and encrypted external hard drive.

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

(•) **Yes** ( ) No

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

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

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

We will be using an external version of RedCap through UCLA to collect all survey data. We will only use participant primary codes, and no names or other identifying information will be input or stored in RedCap.

Box, a secure and encrypted server provided by UCLA, will also be used to store participant video recordings. Video recordings are stored on Box in a separate folder, using the participant's secondary code.

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

Agree [x]

ID: IRB#20-000295 View: NEW 9.3a - Data Security - Identifiable Data

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

Data Security - Identifiable Data

You indicated that personally identifiable information will be maintained with the study data and/or specimens during conduct of the study (Section 9.3/item 3). Please complete the following items.

1.0 ***Will any personally identifiable data be stored on portable devices (e.g., laptops, PDAs, iPods, external hard drives)?**

(•) **Yes** ( ) No

1.1 **If yes, provide the rationale for keeping personally identifiable information on a portable device(s):**

All data will be backed up on external hard drives. These hard drives are encrypted and locked in a secure filing cabinet in the lab and are not taken out of the lab.

The only data that leaves the lab is that which is stored on Box.

2.0 **Indicate how the information will be handled and stored to assure confidentiality.**

2.1 ***Electronic Data:**

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

2.2 ***Hardcopy Data, Recordings and Specimens:**

- [x] **Locked file cabinet or locked room with limited access by authorized personnel**
- [ ] Locked lab/refrigerator/freezer with limited access by authorized personnel
- [ ] Other
- [ ] **Not Applicable**

2.3 **If you indicated "Other" in item 2.1 or 2.2 above, describe here:**

3.0 ***By checking this box, I provide my assurance that all the person(s) who will have access to the personally identifiable information have been identified in section 1.1 or section 1.1a.**
Agree ☑

This view has been locked by amendment(s)

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

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

- [x] **Locked file cabinet or locked room with limited access by authorized personnel**
- [ ] Locked lab/refrigerator/freezer with limited access by authorized personnel
- [x] **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.**

Deidentified electronic data is kept on the computers in the lab (accessed only by the research team), on a password protected secure network server, and on CD's and external drives kept in a locked filing cabinet, in our locked lab in Pritzker Hall.

Personally identifiable information collected includes contact information and video recordings. Contact information is maintained on a secure server in a separate folder to deidentified data, and is not paired with the participant codes. Video recordings are stored on two locked and encrypted external hard drives and CD's using the participant's primary code, and on a secure server in a separate folder to deidentified data using the participant's secondary code.

Names are paired with primary and secondary participant codes only on a password-protected encrypted database, stored on an external harddrive, locked in a secure location in the lab.

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#20-000295 View: NEW 9.5 - Data Security Plan

This view has been locked by amendment(s)

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:

- [ ] All data files will be stripped of personal identifiers and/or the key to the code destroyed.
- [ ] All specimens will be stripped of personal identifiers and/or the key to the code destroyed.
- [x] **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.
A master code linking participant codes to names will be kept in a password-protected file on an external hard drive, kept in a locked file cabinet at our lab (Pritzker Hall 5581). Only research personnel will have access to the code.

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.
Only the research staff has access to personal identifying information. Research staff will receive regular training on being compliant with privacy and confidentiality rules.

ID: IRB#20-000295 View: NEW 9.8 - Data and/or Specimens for Possible Future Use

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

Data and/or Specimens for Possible Future Use

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

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

Check all that apply:

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

2.0 Distribution Rules: Describe the criteria used to determine the adequacy of requests to obtain data and/or specimens (e.g., the type of researchers that will be eligible to receive data):
Coded data from this study will be placed on the Open Science Framework and on GitHub, which is the gold standard practice for psychology research. Anyone with a GitHub account can access the coded (de-identified) data.

ID: IRB#20-000295 View: NEW 10.1 - Study Summary - Research Study

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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 #
asc.pdf	0.01
bdi.docx	0.01

Document Name	Document Version #
bfi_44.pdf	0.01
bfq.docx	0.01
bss.pdf	0.01
ccfq.pdf	0.01
covid_objective.docx	0.01
covid_subjective.docx	0.01
ctq.pdf	0.02
dsm_5.pdf	0.01
gastrointestinal_disorders.docx	0.01
hai.pdf	0.01
info.docx	0.01
info.docx	0.01
ipaq.pdf	0.01
ius.doc	0.01
leq.pdf	0.01
maia.pdf	0.01
med_check.docx	0.01
media_consumption_questionnaire .docx	0.01
menstrual_cycle.docx	0.01
mental_health_history.docx	0.01
panas.pdf	0.01
pedsql_gi.pdf	0.01
pill.pdf	0.01
psqi.pdf	0.01
pss.pdf	0.01
psst.pdf	0.01
ptgi.pdf	0.01
references.docx	0.01
rome.docx	0.01
sasrq.pdf	0.01
scq.docx	0.01
somatic_symptoms.pdf	0.01
somna.docx	0.01
stai.docx	0.01
subjective_social_status.pdf	0.01
timeline.docx	0.01
uclals.pdf	0.01
usq.pdf	0.01
written_response.docx	0.01

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

This study will explore the relationship between somatic symptoms and emotions, using questionnaires and electrogastrography. The specific aims of this study are to (1) establish a relationship between emotions and somatic symptoms, (2) examine how specific somatic symptoms in the context of COVID-19 stress may relate to mental health, (3) investigate individual differences that might influence the emotional response to psychological stress, (4) establish a relationship between emotionally arousing stimuli and the EGG response, (5) investigate the individual differences that might influence the EGG response to stress (such as early life stress, current stress, trait variables, etc.), (6) examine how the EGG response sits with other physiological indices (such as heart rate and sweat response), and (7) explore the ways in which physical sensations are associated with emotions and physiological responses.

The study will test several hypotheses.

1 - Establish a relationship between emotions and somatic symptoms
- Higher perceived stress during the outbreak of COVID-19 will be associated with greater somatic symptomology on the somna.

- Increased interoceptive awareness since the onset of COVID-19 will be associated with greater somatic symptomology
- Increased health anxiety since the onset of COVID-19 will be associated with greater somatic symtpomology

2 - Examine how specific somatic symptoms in the context of COVID-19 stress may relate to mental health.
- Somatic symptomology will mediate the relationship between perceived stress and anxiety, depression, and panic.

3 - Investigate individual differences that might influence the emotional response to COVID-19 stress (such as early life stress, social support, media consumption, diet and exercise, lifestyle habits, trait variables, etc.).
- Early life stress will be associated with an increased emotional response to COVID-19 stress.
- Social support, lifestyle habits (such as sleep, diet, and exercise), personality traits, and media consumption will moderate the association between current stress and emotional response.

4 - Establish a relationship between emotionally arousing stimuli and the EGG response.
- There will be a greater EGG response (i.e. average peak amplitude) for the sad and scary movie condition relative to the neutral movie condition.
- The intensity of subjective emotion will be positively correlated with EGG response.

5 - Investigate the individual differences that might influence the EGG response to stress (such as early life stress, current stress, trait variables, etc.)
- Increased levels of emotional distress, such as anxiety and depression, will be associated with greater EGG response during the emotionally arousing movie conditions.
- Early life stress may be associated with greater EGG response in the emotionally arousing movie conditions, relative to individuals who did not experience early stress.
- Greater current and perceived stress will be associated with greater EGG response in the emotionally arousing conditions.

6 - Examine how the EGG response sits with other physiological indices (such as heart rate and sweat response)
- The EGG response will be associated with other physiological indices of emotional arousal, such as heart rate and sweat response.

7 - Explore the ways in which physical sensations are associated with emotions and physiological responses
- Lower interoceptive awareness will be associated with greater physiological responses to emotionally arousing stimuli.
- Higher somatic symptomology will be associated with greater physiological responses to emotionally arousing stimuli.
- Distinct dimensions of physical sensations and physiological responding will be positively correlated.
- Gastrointestinal symptoms will be associated with both greater anxiety and greater EGG response to emotionally arousing stimuli.

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.

While we often describe our emotions as “gut feelings”, surprisingly little research has examined how emotions and the gastrointestinal system interact. Given the onset of a global pandemic, the situation provides a unique opportunity to investigate how an emotion inducing real-world event, COVID-19, might influence somatic symptoms and the stress response.

Prior research during public health crises such as the SARS epidemic in 2006 reveal that the stress associated with quarantine during the epidemic was associated with higher symptoms of acute stress disorder and later post traumatic stress symptoms (Bai et al. 2004). However, research also reveals that in the wake of the SARS epidemic, individuals found their friends and family members more supportive (Lau et al. 2006). Similarly, research suggests that social support obtained through social interactions after the events of September 11th, 2001, reduced college students’ symptoms of both depression and physical illness (MacGeorge et al. 2004).

Given that gastrointestinal and mental heath problems are highly comorbid, with anxiety five times higher in individuals with irritable bowel syndrome (IBS) than in those with no IBS symptoms (Lee et al., 2009), gastrointestinal and somatic symptoms may serve as a useful indicator of emotional functioning, particularly

during this period of heightened awareness of physical health amid the COVID-19 pandemic. For example, stress in early life can affect both emotional and gastrointestinal symptoms and functioning. One study demonstrated that previous adverse care experiences were associated with both increased anxiety and incidence of gastrointestinal symptoms in youth (Callaghan et al., 2019). In addition, early adversity was associated with changes in gastrointestinal microbiome diversity that were correlated with neural activation to emotional faces (Callaghan et al., 2019).

Physiological methods such as heart rate and sweat response are common indicators of emotional arousal, but the electrograstrogram (EGG) is seldom used in psychological research. In one study, researchers found that movie clips capturing emotions of fear, disgust, and sadness, elicited a greater EGG response relative to a neutral condition (Vianna & Tranel, 2006).

Few studies have explored the way that individual differences including early stress, social support, media consumption, and lifestyle factors may mitigate or exacerbate the negative somatic psychological impact of a stressor as well as the way that these variables and emotional functioning may influence the EGG response to negatively emotionally arousing movie clips.

Using questionnaires and electrogastrography, we seek to investigate the relationship between somatic symptoms (particularly gastrointestinal symptoms) gastric myoelectrical activity, and emotional functioning, in the context of a public health crisis as well as during emotionally arousing movie clips. We also hope to explore factors that might influence gastrointestinal responses to emotional arousal, and whether and how physical sensations are associated with emotions and physiological responses. We also hope to evaluate how EGG sits with other physiological measures, such as heart rate and sweat response, in order to explore whether emotional patterning of physiological responses contribute to meaningful differences in emotion regulation, the stress response, and mental health.

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

Two assessments (the first with one part and the second with two parts) will occur with participants recruited from the psychology department subject pool. The target sample size takes attrition and data loss due to failure to follow instructions or movement into account. Two-hundred participants will be recruited for a target sample of 150 participants. The study consists of three research sessions - two online sessions and a lab session. After participants enroll in the study, they will be contacted by a researcher.

The study begins with a researcher sending the participant the information sheet to review. Any questions will be answered at this time.

Part 1:

The researcher will send the participant a link to complete electronic surveys via REDCap. Participants will be asked to complete the questionnaires listed below at home. The questionnaires assess domains of physical symptoms, diet, adversity exposure, emotion/mental health, stress, social support, media consumption, lifestyle changes, and general demographics. Any questions on suicidal ideation or intent have been removed.

-Information (info) - Assesses demographics, health, and location information
-COVID objective (covid_objective) - Assesses the objective impact of COVID-19 including infection, quarantine, household, social distancing etc.
-Somatic markers of negative affect (somna) - Assesses physical sensations of anxiety and sadness, where they are located, and their intensity
-Multidimensional assessment of interoceptive awareness (maia) - Multidimensional self-report measure of interoceptive body awareness
-Health anxiety inventory (hai) - Assesses people's anxiety about health symptoms (hypochondriasis).
-Somatic symptoms(ss) - Assesses a range of somatic symptoms in adult participants
-Pennebaker inventory of limbid languidness (pill) - Measures people's tendency to notice and report a braod array of physical symptoms and sensations.
-Pediatric quality of life gastrointestinal symptoms module (pedsql_gi) - Assess incidence of Gastrointestinal Symptoms
-Medication checklist (med_check) - Inventory of current medications, dosage, length of time on medication, and dosage changes.
-Gastrointestinal disorders (gastrointestinal_disorders) - Assesses gastrointestinal issues, their frequency and intensity
-Rome (rome) - Assesses the presence of symptoms which meet criteria for irritable bowel syndrome as stated by the Rome IV

-Menstrual cycle questionnaire (menstrual_cycle) - Assesses menstrual phase, which affects gastrointestinal responding, as well as medications which may affect menstrual phase such as oral contraceptive use
-Premenstrual symptoms screening tool (psst) - Assesses premenstrual syndromes and criteria for premenstrual dysphoric disorder (pmdd) as well as premenstrual syndrome (pms).
-COVID subjective (covid_subjective) - Assesses the subjective impact of COVID-19 on well-being.
-Stanford acute stress reaction questionnaire (sasrq) - Assesses the psychological symptoms experienced in the aftermath of a traumatic event.
-Perceived stress scale (pss) - Helps us understand how different situations affect our feelings and our perceived stress. The questions in this scale as about your feelings and thoughts during the last month.
-Childhood trauma questionnaire (ctq) - The Childhood Trauma Questionnaire is a brief survey of six early traumatic experiences (death, divorce, violence, sexual abuse, illnesss, and upheaval).
-Life events questionnaire (leq) - Asks about recent stressful life events.
-Undergraduate stress questionnaire (usq) - The undergraduate stress inventory presents students with various stressors and asks them to indicate if any of the events have happened to them. They are also asked how stressed they are by this event.
-Cognitive control and flexibility questionnaire (ccfq) - Measures an individual's percevied ability to exert control over intrusive, unwanted (negative) thoughts and emotions, and their ability to flexibly cope with a stressful situation.
-Post traumatic growth inventory (ptgi) - An instrument for assessing positive outcomes reported by persons who have experienced traumatic events.
-State trait anxiety inventory (stai) - The State-Trait Anxiety Inventory (STAI) is a commonly used measure of trait and state anxiety. It can be used in clinical settings to diagnose anxiety and to distinguish it from depressive syndromes. It also is often used in research as an indicator of caregiver distress
-Beck depression inventory (bdi_ii) - Developed for the assessment of symptoms corresponding to criteria for diagnosing depressive disorders listed in the DSM IV
-Mental health history (mental_health_history) - A questionnaire to assess mental health history
-Adolescent social connection and coping during COVID-19 - This questionnaire is designed to learn about the ways you connect with people, and how it makes you feel. This might be affected by the COVID-19 outbreak, especially when following physical distancing or shelter-in-place orders.
-UCLA loneliness scale (uclals) - A 20-item scale designed to measure one’s subjective feelings of loneliness as well as feelings of social isolation.
-Social cravings questionnaire (scq) - A measure designed to address social cravings.
-Big five personality inventory (bfi_44) - Inventory that measures an individual on the big five factors of personality (extraversion, agreeableness, conscentiousness, neuroticism, and openness to experience).
-Intolerance of uncertainty scale (ius) - The Intolerance of Uncertainty Scale includes items relating to the idea that uncertainty is unacceptable, reflects badly on a person, and leads to frustration, stress, and the inability to take action
-Pittsburgh sleep quality index (psqi) - The Pittsburgh Sleep Quality Index (PSQI) is an effective instrument used to measure the quality and patterns of sleep in adults. It differentiates “poor” from “good” sleep quality by measuring seven areas (components): subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction over the last month.
-Timeline questionnaire (timeline_questionnaire) - Assesses how participants spend an average day in hour increments. Free response.
-Brief food questionnaire (bfq) - Assesses participants consumption of food groups.
-International physical activity questionnaire (ipaq) - Asks questions on physical activity.
-Positive and negative affect schedule (panas) - Positive and Negative Affect Schedule is a self-report questionnaire that consists of two 10-item scales to measure both positive and negative affect. Each item is rated on a 5-point scale of 1 (not at all) to 5 (very much).
-Written response (written_response) - This prompt asks participants to write about their thoughts and feelings regarding an emotional event.

In the following academic term participants will be recontacted for participation in part 2. Additional participants will be recruited to account for attrition.

Part 2:

The researcher will send the participant a link to complete electronic surveys via REDCap. Participants will be asked to complete the questionnaires listed below at home. The questionnaires assess domains of physical symptoms, diet, adversity exposure, emotion/mental health, stress, and general demographics. Any questions on suicidal ideation or intent have been removed.

-Information and Demographics (info) - asks basic demographic questions such as age, sex, gender, ethnicity, highest educational level attained, time of last meal, and typical diet
time of last meal and diet)
-Pediatric Quality of Life Gastrointestinal Symptoms Module (pedsql_gi) - Assess incidence of Gastrointestinal

Symptoms and fatigue
-Bristol Stool Scale (bss) - Assesses typical stool type using a range of images
-Rome IV Criteria Questionnaire (rome) - Assesses the presence of symptoms which meet criteria for irritable bowel syndrome as stated by the Rome IV
-Gastrointestinal Disorders Questionnaire (gastrointestinal_disorders) - Assesses gastrointestinal issues, their frequency and intensity
-The Positive and Negative Affect Schedule (panas) - is a self-report questionnaire that consists of two 10-item scales to measure both positive and negative affect.
- State Trait Anxiety Inventory (stai) - The STAI is a commonly used measure of trait and state anxiety. It can be used in clinical settings to diagnose anxiety and to distinguish it from depressive syndromes.
-Beck Depression Inventory (bdi_ii) - Developed for the assessment of symptoms corresponding to criteria for diagnosing depressive disorders listed in the DSM IV.
- Cross Cutting Symptom Questionnaire (dsm_5) - This measure assesses the presence of a range of symptoms that are common across diagnostic categories in mental illness (e.g., sleep disturbances). It can be used to monitor change across time in mental health without referring to specific diagnoses.
-Life Events Questionnaire (leq) – The LEQ is a checklist of potentially adverse but everyday life events (e.g., death of a pet/grandparent) that has occurred in the last 12 months, and in their lifetime.
-Childhood Trauma Questionnaire (ctq) is a brief survey of six early traumatic experiences (death, divorce, violence, sexual abuse, illness or other), and assesses individual's understanding of their childhood trauma.
-stressful_events
-Perceived Stress Scale (pss) - Helps us understand how different situations affect our feelings and our perceived stress
-Medication Checklist (med_check) – Participants are asked to list all medications that they are on. This information is used as a covariate in analyses of physiological data, as different medications can affect the readouts from these assays/analyses.
-Menstrual Cycle Questionnaire (menstrual_cycle) - Assesses menstrual phase which affects gastrointestinal responding as well as medications which may affect menstrual phase such as oral contraceptive use
-Somatic Symptom Questionnaire (somatic_symptom) - Assesses a range of somatic symptoms in adult participants
-Premenstrual Symptoms Screening Tool (psst) - Assesses premenstrual syndromes and criteria for premenstrual dysphoric disorder (pmdd) as well as premenstrual syndrome (pms).
-Multidimensional assessment of interoceptive awareness (maia) - multidimensional self-report measure of interoceptive body awareness
-Somatic Markers of Negative Affect (somna) - Assesses physical sensations of anxiety and sadness, where they are located, and their intensity
-Media consumption questionnaire (media_consumption_questionnaire) - Assesses traditional and digital media use and consumption

Participants will then come into the lab for a lab session. The lab sessions will all be scheduled from 12 p.m. - 6 p.m. and participants will be instructed not to eat for one hour prior to the session (due to confounds with gastrointestinal recordings after meals). Participants will be given a bottle of water, and a trained researcher will apply the physiology electrodes (explained below).

Participants will then have their height, weight, and waist circumference measured by a researcher.

Participants will then watch a series of 3 20 minute montages of short movie clips with an intended emotion. There will be a sad, neutral, and scary condition, and these conditions will be counterbalanced across subjects. The physiology equipment will make the following recordings.

Heart Rate: Participants will have their heart rate recorded using a Biopac recording device. Two small stickers containing a recording electrode are placed on the front of participant’s bodies (underneath their collarbone on the left and right side). A third sticker, also containing a recording electrode, will be placed on participant’s left lower rib. The electrodes are attached to recording wires, which lead to the Biopac machine, which is itself hooked up to a computer. Participants will be watching a series of ‘scary’/'sad'/'neutral' movie clips.

Electrogastrogram (EGG): Participants will have their gastric activity monitored through an EGG. Similar to measures of heart rate, the EGG is collected through small stickers containing recording electrodes that are stuck on the abdomen, and are connected through recording wires to the Biopac machine and then computer. EGG will be measured at the same time as participants heart rate, and so children and adolescents will be watching the same movies as described above.

Galvanic Skin Response (GSR): Participants will have their GSR (sweat) response measured while they are watching the movie clips. GSR is measured by small stickers with electrodes that are placed on the participants hand to measure very small variations in sweating (which are a marker of attention). Two stickers are placed on the participants non-dominant hand, with wires leading to the Biopac machine and computer.

After each 20 minute montage, participants will complete the panas questionnaire, to assess the induction of the intended emotion.

After the three montages are finished, the participant will be debriefed.

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

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

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

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

○ Yes ○ No

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

The online session in part 1 will take approximately 2 hours.

The online session in part 2 will take approximately one hour and the lab session will take approximately 1.5 hours. Therefore, participants can expect to spend 2.5 hours total participating in this study.

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

The study will be preregistered on OSF.io and deidentified data will be shared publicly through osf.io.

A factor analysis will be performed to validate the somatic markers of negative affect (somna) questionnaire against other measures of somatic symptoms.

We will determine whether somatic symptomology mediates the relationship between perceived stress and anxiety and depression.

Variables such as social support, lifestyle factors, media consumption, personality factors will be explored as moderators of mental health outcomes amid the current stress of the global pandemic.

Average measures of physiology will be compared in the different movie conditions to determine whether a significantly different physiological response is present in the emotionally arousing compared to neutral conditions.

Physiological responses will also be compared in relation to measures of early stress. Regression models will be utilized to determine if early stress predicts level of physiological responding (particularly EGG response) to emotionally arousing stimuli. We will also utilize regression to determine if current stress predicts physiological response, and whether this association is moderated by early stress.

We will compare our various physiological indices using regression to determine how closely they align together. We will use data driven approaches to explore physiological profiles and their relationships to other variables such as stress, anxiety, depression, and interoceptive awareness. Finally, we will utilize regression to determine the relationship between gastrointestinal symptoms and physiological responding, and whether this association is moderated or mediated by anxiety, depression, early experiences etc.

This view has been locked by amendment(s)

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

Characteristics of the Study Population

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

○ Yes ◉ **No**

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

150

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

200

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.
Participants must be age 18 or over to participate and fluent in the English language. Our laboratory is only capable of interacting with people who are fluent in English.

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.
Individuals with uncorrected vision and/or hearing cannot participate due to the fact that stimuli are presented audiovisually.

6.0 ***How (chart review, additional tests/exams for study purposes, etc.), when and by whom will eligibility be determined?**
These eligibility requirements will be restricted via the participant subject pool. If eligible, participants can sign up online and will be sent a unique link to access the home session questionnaires via REDCap. These participants will be recontacted in the following academic term. Participants must complete the online session questionnaires before their scheduled lab session time to participate and receive course credit. If a potential participant or enrolled participant ends up not being enrolled, or leaves the study, we will destroy all of their research materials, including their screening information.

Additional participants will be recruited in part 2 to meet sample size requirements (due to attrition).

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
- [x] **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**

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

UCLA Students or UCLA Faculty/Staff

You indicated that this study includes UCLA Students or UCLA Faculty/Staff (Section 11.2/item2). Please provide the following information.

1.0 **UCLA Students**

If you indicated that UCLA Students will be included in the research, please respond to the following items.

1.1 **Does the investigator have grading or supervisory responsibilities for some or all of the students that will be recruited for the study?**

(●) **Yes** ( ) No

1.1.1 **If yes, provide justification for recruiting your own students.**

Some students of the principal investigator, Dr. Bridget Callaghan, may participate in this research through the participant subject pool. However, there will be a number of research projects from which to choose and and participation In this research project is not necessary for the course.

2.0 **UCLA Faculty/Staff**

If you indicated that UCLA Faculty/Staff will be included in the research, please respond to the following items.

2.1 **Will you be recruiting staff or faculty from your own lab or office?**

( ) Yes ( ) No

2.1.1 **If yes, provide justification for recruiting employees from your office or lab.**

ID: IRB#20-000295 View: NEW 14.1 - Risks & Benefits

This view has been locked by amendment(s)

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.**

The results of this study may improve our understanding of how emotions are related to gastrointestinal activity and somatic symptoms. In addition this study will help us understand what factors might mitigate or exacerbate the physical and psychological response to stress. This study will help us understand how gastrointestinal activity is related to other physiological indices such as heart rate and sweat response. It will also help us understand how early life experiences may contribute to these associations. This information might be used to better interventions and treatments for individuals who are suffering from anxiety, depression, and physical health problems, particularly in times of heightened stress or trauma.

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.

Questionnaires: There is a small risk of participants becoming upset by the questions asked in the questionnaires during the home session.

Movies: There is a small risk of participants becoming upset by the scary and sad movie clips shown during the lab session.

Measures to minimize risks: Participants will be fully informed of the potential risks of this study, and will provide informed consent prior to participating.
If participants become upset during any stage of the protocol, we will stop the protocol and provide referral information for psychological services.

In addition, we will include links to psychological services at the conclusion of the surveys.

Risk/Benefit Analysis

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

While there are only minor risks associated with participation in this study, the potential benefits to society include adding to the existing knowledge base on the interaction between mental and physical health and environmental influences of stress. The results from these studies will contribute towards improving existing interventions, and developing novel interventions for those who are currently suffering from anxiety and other mental and physical health problems or experiencing stress or trauma. It is our opinion that the potential benefits to participants and society greatly outweigh the risks involved in this type of investigation.

Alternatives

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

Check all that apply.

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

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

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

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

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#20-000295 View: NEW 16.1 - Payment, Costs, and Injury

This view has been locked by amendment(s)

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
- ☐ 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.

For Part 1 of the study, participants will receive 2 course credits.

For Part 2 of the study, participants will receive 3 course credits.

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

○ Yes ◉ **No**

3.1 **If yes, describe:**

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

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

- ◉ **Agree**
- ○ Not Applicable

ID: IRB#20-000295 View: NEW 18.1 - Identification/Recruitment Methods

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

Identification/Recruitment Methods

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

Check all that apply:

- ☐ Advertisements/Flyers/Information Sheet/Internet Postings
- ☐ Direct recruitment of potential study participants (e.g., physicians talking with their own or clinic patients about the study, contact between the study team and potential subjects in person, on the phone or on the internet, etc.)
- ☐ Random or Other Probability Sampling
- ☐ Recruitment Letters/Emails
- ☐ Referrals (e.g., referrals from non-investigator healthcare providers, snowball sampling, participants referring other participants, etc.)
- ☐ 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#20-000295 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 #
SONA_advertisement.doc	0.02

Ads/Flyers/Info Sheets/Internet Postings

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

Direct Recruitment

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

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

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.

Recruitment Letters/Emails

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

Referrals

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

Research Participant Pools/Recruitment Databases

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

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

Eligibility Screening

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

○ Yes ◉ **No**

ID: IRB#20-000295 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:

☐ **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#20-000295 View: NEW 20.2 - Waiver of Signed Informed Consent (Consent Without a Signature)

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

Waiver of Signed Informed Consent (Consent Without a Signature)

You indicated that you are obtaining oral consent for the study (Section 20.1/item 1). Please provide the following information.

1.0 ***Indicate the reason that you are requesting to conduct an oral consent process instead of obtaining signed consent.**

- (●) **The research is minimal risk and does not involve any procedures for which written consent is normally required outside the research setting (e.g., in everyday life written consent is not needed for minimal risk surveys, non-invasive health measurements, etc.) (45 CFR 46.117 c2)**
- ( ) The only record linking the participants and the research would be the consent document, and the main risk of research would be a breach of confidentiality (45 CFR 46.117 c1).

  e.g., Participants could suffer from social stigma, embarrassment, or other harms if it became known that they participated in research that identified them as having issues including, but not limited to, risky sexual behaviors, HIV, or mental health problems.

If you indicated that the **main risk is a breach of confidentiality**, answer 1.1, if appppropriate.

1.1 **According to DHHS regulations at 45 CFR 46.117 (c1) when the main risk of the research would be a breach of confidentiality and an oral consent process is used, each subject should be asked whether he/she wants documentation linking the subject with the research and the subject's wishes will govern.**

Check here if you want the IRB to consider allowing a waiver of this regulation so that you do not need to ask each subject if he/she wishes documentation.

- [ ] Request to waive documentation linking the participant with the research

2.0 **If the oral consent process applies only to certain parts of the study (e.g., specific procedures or populations), explain.**

ID: IRB#20-000295 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
- [ ] In a private room
- [ ] In a waiting room
- [ ] In a public setting
- [ ] In a group setting
- [x] **On the internet**
- [ ] Over the telephone

- [ ] Other

1.1 **If you checked more than one response, or indicated other, describe.**
Because the first part of the study is conducted online, participants will review an information sheet via email before completing the first online session.

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.
- [ ] Prospective participants/families will have the opportunity to take the consent form(s) home and may discuss the documents with others prior to deciding whether or not to participate in the study.
- [x] **Prospective participants will self-administer the consent and send it back if they decide to participate in the study.**
- [ ] Other

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

3.0 ***Indicate the length of time subjects are given to decide whether they wish to participate in the study.**
Participants will receive an information sheet over email after they have enrolled. They will be allowed as much time as they would like to review the information sheet and ask questions. Procedures will commence after the information sheet has been reviewed.

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

Check all that apply.

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

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

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

Document Name	Document Version #
information_sheet.doc	0.02
information_sheet_marked.doc	0.02

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

Cultural Considerations

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

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

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

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

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.**

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#20-000295 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#20-000295 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#20-000295 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#20-000295 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#20-000295 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#20-000295 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#20-000295 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.

ID: IRB#20-000295 View: Display - Method Description

Drugs/Biologics/Dietary Supplements

- Drug: The term "drug" means: articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to

any of them; and articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and articles (other than food) intended to affect the structure or any function of the body of man or other animals.

- Biologics vs. Drugs: Most drugs consist of pure chemical substances and their structures are known. Most biologics, however, are complex mixtures that are not easily identified or characterized. Biological products differ from conventional drugs in that they tend to be heat-sensitive and susceptible to microbial contamination. This requires sterile processes to be applied from initial manufacturing steps. For more information see: http://www.fda.gov/consumer/updates/biologics062608.html#drugs
- Dietary Supplements are products that are intended to supplement the diet and have one of the following ingredients:
    - ☐ A vitamin
    - ☐ A mineral
    - ☐ An herb or other botanical
    - ☐ An amino acid
    - ☐ A dietary substance for use by man to supplement the diet by increasing the total daily intake
    - ☐ A concentrate, metabolite, constituents, or an extract of combinations of these ingredients.

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

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

ID: IRB#20-000295 View: Display - Method Description

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

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

ID: IRB#20-000295 View: Display - Method Description

Genetic Analyses/Genotyping

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

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

ID: IRB#20-000295 View: Display - Method Description

Human Embryonic Stem Cells and/or Induced Pluripotent Stem Cells

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

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

ID: IRB#20-000295 View: Display - Method Description

Human Gene Transfer/ Recombinant DNA

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

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

ID: IRB#20-000295 View: Display - Method Description

Infectious Agents

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

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

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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.

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

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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

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

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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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