

**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:**

Dynamic Public Goods

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

**2.0 \*Working or Lay Title:**

Dynamic Public Goods

**3.0 Principal Investigator:**

**3.1 \*Name:** FLORIAN EDERER

Degree(s):

PhD

**3.2 UCLA Title:**

**3.3 Affiliation(s):** There are no items to display

**Other Affiliations:**  
(if provided)

**3.4 Department:** ANDERSON GRAD SCH OF MANAGEMENT  
**Secondary Department:**

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

Yes

No

Not Applicable

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

Yes  No

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

**3.7 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 at item 3.6.1 above.**

**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.**

FSTFI A HOPFNHAYN

**5.0 List the UCLA Principal Investigator, key personnel, and study staff below.**

**Note:** All personnel listed below are required to complete CITI training courses. HIPAA training is also required if personnel will be accessing protected health information.

Name	Department	Role	Other Role (if applicable)	Will Obtain Consent?
View GEORGIOS GEORGIADIS	ANDERSON GRAD SCH OF MANAGEMENT		Co-Investigator	no

ID: IRB#12-000510

View: NEW 1.1a - Other Personnel

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**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 \*If there will be other types of personnel working directly under the PI's supervision on aspects of the study, provide their name, indicate their responsibilities and complete Item 1.2.**

**Note: If there will not be other types of personnel go to Item 2.0.**

Name, title, institution	Study role(s): e.g., conduct interviews/surveys, recruit participants, obtain consent, review records, etc.
View Estela Hopenhayn, Lab Manager, CASSEL	

For existing protocols: Item 1.0 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 1.0 above.

Briefly describe the other study personnel.

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

Check all that apply:

CITI Training

UC HIPAA Training

Other

- 1.2** If you indicated "Other" to item 1.1, describe:

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

Yes  No

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

ID: IRB#12-000510

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:**

<b>Document Name</b>	<b>Document Version #</b>
----------------------	---------------------------

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:**

<b>Document Name</b>	<b>Document Version #</b>
----------------------	---------------------------

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:**

<b>Document Name</b>	<b>Document Version #</b>
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There are no items to display

ID: IRB#12-000510

View: NEW 2.1 - Project Identification Information

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

**Project Identification Information**

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

Research Study  
 Application for Approval of "Research Participant Pool" or recruitment database only

- 2.0 \*Type of Submission (Select one)**

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 Review For and Reliance Upon External IRBs.**

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

None of the options below apply.  
 Request for UCLA IRB to review for an(other) UC campus: If UCLA investigators are collaborating with (an)other UC(s) and the UCLA IRB will conduct the IRB review, select this option. Attach required form in Item 3.1.  
 Request for UCLA IRB to review for RAND: If UCLA investigators are collaborating with RAND on health services research and the UCLA IRB will conduct the IRB review, select this option and attach the required form in Item 3.1.

- If UCLA investigators are collaborating with another institution within the **Clinical and Translational Science Institute (CTSI)** select this option and attach the required form in Item 3.1.
- Request for UCLA to serve as IRB of record for collaborators for federally funded research. Contact the OHRPP Director or Assistant Directors to make the request.
- Request for UCLA IRB to rely upon NCI IRB review:** If IRB review is delegated to the **National Cancer Institute (NCI) Central IRB**, select this option. *Additional information will be requested in Section 4.1.*

**Important Note:** If you wish to request that UCLA rely upon an external IRB not outlined above, do not submit an application in webIRB. Contact the OHRPP Director or Assistant Directors to make a formal request. See also [Reliance of UCLA Investigators on External IRBs](#) for information about existing UCLA agreements.

**3.1 Documentation Required for UCLA to Serve as Reviewing IRB**

See OHRPP website: [External IRBs](#) for the criteria for eligibility for UC MOU, RAND/UCLA MOU, and CTSI IRB deferral mechanisms, and the related required application forms.

**If applicable, upload a completed copy of the required forms to request that UCLA serve as reviewing IRB or IRB of record.**

Document Name	Document Version #
There are no items to display	

**4.0 \*Federal regulations (45 CFR 46.111) require scientific review before an IRB approves a study. Has or will this study receive a scientific or scholarly review?**

Yes  No

**4.1 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

**4.1.1 If you checked "other", describe.**

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

Document Name	Document Version #
There are no items to display	

ID: IRB#12-000510

View: NEW 2.2 - Lay Summary and Keywords

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

## Lay Summary and Keywords

Please provide the following information about your study.

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

The objective of this study is to experimentally investigate how the collaboration among a group of agents evolves over time in a

joint project which pays out a reward to the agents upon completion. In particular, we focus on three key questions. First, we examine how the members' incentives to contribute in the project depend upon how close the project is to completion. Second, we investigate how the size of the team affects the members' incentives to contribute at different stages of the project. Third, we examine how with two-member teams, unequal compensation affects the members' incentives to contribute.

- 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.**

incentives to contribute, unequal compensation, collaboration

- 3.0 \*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 and/or involves gene therapy?

Yes  No

**Note:** If you answered "Yes" in Item 3.0, 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 4.2 of the webIRB application.

ID: IRB#12-000510

View: NEW 5.1 - Type of Study Review

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

## Type of Study Review

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

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

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

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

- Expedited  
 Exempt  
 Full Board

- 2.1 If you indicated expedited or full board as the type of review in item 2, choose an IRB assignment.**

Name	Description
<input type="radio"/> Medical Institutional Review Board 1	MIRB1 reviews general and internal medicine, infectious diseases, and dental and ophthalmologic research.
<input type="radio"/> Medical Institutional Review Board 2	MIRB2 reviews oncology and hematologic research.
<input type="radio"/> Medical Institutional Review Board 3	MIRB3 reviews neuroscience, neurology, psychiatric, drug abuse, and related behavioral science research.
<input checked="" type="radio"/> North General Institutional Review Board	NGIRB reviews research from the College of Letters & Science and the Professional Schools.
<input type="radio"/> South General Institutional	SGIRB reviews social-behavioral research from South campus researchers who conduct health services research in areas such as public health, quality of care, quality of life, health education and health behavior.

ID: IRB#12-000510

View: NEW 5.2 - Expedited Review

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

## Expedited Review

You have indicated that you are requesting an expedited review for this study (Section 5.1/Item 2). Please provide the following information.

- 1.0 \*Select the applicable category(ies) of studies eligible for expedited review from the list below (click on the link to see the full description).**

**Check all that apply.**

- (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows
- (3) Prospective collection of biological specimens for research purposes by non-invasive means
- (4) Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves
- (5) Research involving materials (data, document, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes
- (6) Collection of data from voice, video, digital, or image recordings made for research purposes
- (7) **Research on individual or group characteristics or behavior**
- (1) Clinical studies of drugs and devices only when condition (a) or (b) is met
- (8) Research which was previously reviewed by the convened IRB, but meets the criteria for Expedited review and meets one of the following categories for Expedited review as defined by OHRP and the FDA
- (9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply

ID: IRB#12-000510

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](#).

### 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.

ID: IRB#12-000510

View: NEW 6.2 - Funding - Description

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

## Funding - Description

*Based on the response to section 6.1/item1, this study is or will be funded. Please provide the following information.*

The Office of Contract and Grant Administration (OCGA) provides the list of funding sources used by webIRB in this section. Please check your OCGA paperwork to find the correct name of the funding source(s) for this study. Identifying the right funding source is important because:

- webIRB will auto-populate the designated funding source name on the approval letter for the study. Many funding sources require an accurate identification of their name on the IRB approval letter before they will release funding;
- The Office of Research Administration uses data from webIRB to generate funding reports.

[Click here](#) for tips on how to find the funding source name in webIRB.

### 1.0 Identify the funding source(s).

#### Funding Source Information

Source	
<a href="#">View</a>	
<a href="#">Other</a>	
Name of the Funding Source	Other
If other, specify	Anderson School of Management
UCLA PI named on the grant, contract, subcontract or gift:	FLORIAN EDERER
Indicate the type of award:	Other
Indicate the Grant Title:	Dynamic Contribution Game
Indicate the Award Number assigned by the funding source:	No Value Entered
Indicate the description that applies to the source of funding named in the above item. If this is a subcontract, indicate the original source of funding:	Other
If Other, specify	This project is funded by my standard research allowance that I receive from UCLA Anderson. Funding is granted for any study that is approved by UCLA IRB.
If this project is federally funded, attach a copy of the funding proposal, including the budget pages:	

Does the content of this IRB application differ from the activities described in the above-described funding application?	No
If yes, describe:	No Value Entered

ID: IRB#12-000510

View: NEW 7.1 - Study Locations

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

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

**Check all that apply:**

- UCLA Sites or UCLA Health System Sites
- Off Campus (in California)
- Outside the United States
- Outside California
- Internet

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

Yes  No

*If no, please skip directly to the next page, do not complete the questions below.  
If yes, please provide the following information:*

- 2.1 Will the UCLA principal investigator specified on this application be responsible for the overall direction of the study at the other institutions (i.e. UCLA is the Lead institution)?

Yes  No

- 2.1.1 If no, list the other sites that will be participating in this study:

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

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

ID: IRB#12-000510

View: NEW 8.1 - Methods/Procedures - Descriptors

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."****Methods/Procedures - Descriptors**

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

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

- Audio, Visual or Digital Recordings
- Behavioral Observations (only applicable if you selected Exempt Category 2 in section 5.3)
- Certificate of Confidentiality
- Clinical Trial of a Behavioral Intervention (if applicable, select additional related categories)
- Clinical Trial of a Drug, Biologic or Device (You must also specify below "Device/Diagnostics" and/or "Drugs/Biologics/Dietary Supplements")
- Devices/Diagnostics (including Humanitarian Devices - HUD)
- Drugs/Biologics/Dietary Supplements
- Controlled Substances (Schedule I or II)
- Deception or Partial Disclosure
- Human Embryonic Stem Cells and/or Induced Pluripotent Stem Cells
- Non-FDA approved medical equipment used with UCLA hospital patients or research participants that operate under the UCLA Hospital License.
- Genetic Analyses/Genotyping
- Human Gene Transfer/ Recombinant DNA
- Infectious Agents
- Radiation (Standard of Care or Investigational use of radioactive materials or ionizing radiation)
- Substance Abuse Research (with Medication)
- Treatment in an Emergency Setting (with request to waive consent)
- None of the above**

**2.0 \*Check all that apply to the study design.**

- Some of the research activities do not 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). Neither consent nor authorization will be obtained for use of these specimens and/or data.
- 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). Neither consent nor authorization will be obtained for use of the specimens and/or data.
- The research activities involve direct contact with study participants (e.g., collection of data or specimens in person or via internet, phone, mail, etc.)

ID: IRB#12-000510

View: NEW 9.2 - Information about Study Data

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."****Information about Study Data***This information is needed to determine how you will best protect the confidentiality of data.***1.0 \*Indicate all that apply to the study data.****Check all that apply:**

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

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

Yes  No

**2.1 If yes, explain below and include a discussion of the reporting**

**requirements in the consent document:**

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

Records (Not medical)

Human biological specimens

None of the Above

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

Names

Dates

Age (if over 89 years)

Postal Address

Phone Numbers

Fax Numbers

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)

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:

The data and/or specimens will be directly labeled with personal identifying information when acquired by the investigator for this research

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

The 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:

Use for this study only

Use for possible future research

Use to create a bank or repository at UCLA

Add to existing repository

Other

**5.1.1 If Other, specify:**

ID: IRB#12-000510

View: NEW 9.2a - Privacy and Confidentiality

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

## Privacy and Confidentiality

### Important Notes:

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

See OHRPP Quick Guide: Protecting Privacy and Maintaining Confidentiality

**1.0 \*Privacy: How will the investigator maintain privacy in the research setting(s)?**

(e.g., interviewing participant in a room or area where conversations cannot be overheard by others, or conducting medical procedures in an examination room, or behind a curtain in an emergency room)

Data is recorded on the computer as the session proceeds. Payment information will be associated with participant's names so that payments can be made once the session is over. Once the session is over, the decision data is stored independently of the identity of the participants. The decision data will be stored on CASSEL servers. Payment information with participant's names is stored securely and separately by CASSEL. No information that links personal information with the data will be used in published research, but it may be used to track participants through several sessions, or to exclude participants based on participation in past sessions. Participation eligibility for sessions with experienced participants is not based on the specific decisions a participant made in earlier sessions.

The investigator will maintain privacy in the research setting as subjects are seated at computer terminals that have privacy screens. Thus, every subject is only able to see their own choices. Similarly, payment is private.

**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.

CASSEL management will have access to the personal information for administrative purposes. Data with personal information will not be released without the participant's permission unless required by law. When the research has been completed, the data will be retained by CASSEL and an anonymous version of the decision data made available to researchers.

All records of materials will be kept on file by CASSEL staff for 5 years, after which it will be destroyed.

ID: IRB#12-000510

View: NEW 9.3 - Data Security

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

## Data Security

You indicated that the study team will have access to personally identifiable or coded information (Section 9.2/item 4). 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 instances).**

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:**

The data and/or specimens will be coded

The personal identifying information will be removed and destroyed

Personally identifying information will be maintained with the data and/or specimens

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

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

Data will be recorded and stored by the experimenters. Payment information will be associated with participant's names so that payments can be made once the session is over. Once the session is over, the decision data is stored independently of the identity of the participants. Payment information with participant's names is stored securely and separately by CASSEL. No information that links personal information with the data will be used in published research, but it may be used to track participants through several sessions, or to exclude participants based on participation in past sessions. Participation eligibility for sessions with experienced participants is not based on the specific decisions a participant made in earlier sessions. CASSEL management will have access to the personal information for administrative purposes only. Data with personal information will not be released without the participant's permission unless required by law.

**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.

Other.

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

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

Agree

ID: IRB#12-000510

View: NEW 9.4 - Data Security Plan - During the Study

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."****Data Security Plan - During the Study**

You indicated that data and/or specimens for this study will be coded (Section 9.3/item 2). Please complete the following information.

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

Check all that apply:

**1.1** **\*Electronic Data**

- Encryption or password protection software will be used**
- Secure network server will be used to store data**
- Stand alone desktop computer will be used to store data (not connected to server/internet)
- A contracted outside vendor will store the code key. The vendor will have a business associate agreement with UCLA. For information on contracts with vendors to handle research data, see <http://www.ucop.edu/irc/itsec/uc/issues.html>.
- Other
- Not Applicable**

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

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

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

- 2.0** Indicate who will have access to the code key:

- FLORIAN EDERER
- GEORGIOS GEORGIADIS
- ESTELA HOPENHAYN

ID: IRB#12-000510

View: NEW 9.5 - Data Security Plan

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

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

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

Check all that apply:

- All data files will be stripped of personal identifiers and/or the key to the code destroyed.**
- All specimens will be stripped of personal identifiers and/or the key to the code destroyed.
- Personal identifiers and/or codes linking the data and/or specimens to personal identifiers will be maintained for future

research.

- Audio or Video recordings will be transcribed and then destroyed or modified to eliminate the possibility that study participants could be identified.
- Photos or Images will be modified to eliminate the possibility that study participants could be identified.
- Restricted use data will be destroyed or returned to the source.

- 1.1 If you indicated that personal identifiers will be maintained for future research, provide the following information:**
- a) How the information will be securely handled and stored
  - b) assure confidentiality, and
  - c) who will have access to the identifiers and/or codes.

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

ID: IRB#12-000510

View: NEW 10.1 - Study Summary - Research Study

**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 #
Instructions	0.04
Teams and Project Dynamics - Experiment	0.02

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

The objective of this project is to experimentally examine three hypotheses as predicted by Georgiadis (2011). The rest, which will serve as a precursor to the second and main hypothesis that we intend to examine, is that each agent will contribute more, the closer the project is to completion. Intuitively, because agents discount time, they have a stronger incentive to contribute when the project is closer to completion since the expected time between contributing and collecting their reward is smaller. The second hypothesis is that members of a larger team will contribute more (relative to members of a smaller team) if and only if the project is sufficiently far from completion.

Similarly, we expect the aggregate contribution level of a larger team to be higher than that of a smaller team if and only if the project is sufficiently far from completion. Moreover, these results should hold both if the project is a public good, so that each participant's payoff is independent of the team size, and if the project is associated with some pre-specified prize, which is shared equally among the team members as soon as the project is completed.

To understand the intuition behind this result, note that members of a larger team can benefit from sharing the total effort to complete the project among a bigger group, while they also have a larger opportunity to free-ride (i.e., cheat). The former effect is labeled the encouragement effect, while the latter is labeled the free-riding effect. The intuition is that the encouragement effect becomes weaker, while the free-riding effect becomes stronger as the project evolves towards completion. To see why, observe that the benefit from sharing the effort to complete the project is smaller, the closer the project is to completion. On the other hand, agents work harder when the project is closer to completion, and hence they have stronger incentives to free-ride. The upshot is that the encouragement effect is stronger than the free-riding effect if (and only if) the project is far from completion.

**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 are no preliminary data available, briefly indicate why this proposed study is a reasonable starting point.

There is a rich experimental literature that studies the group size effects in voluntary contribution games. In general, these experiments find increased free-riding behavior in larger groups; e.g., Sweeney (1973), Latane, Williams and Harkins (1979) and Harkins, Latane and Williams (1979), which is consistent with the theoretical literature on moral hazard in teams such as Holmstrom (1982), Bonatti and Horner (2011), and others. On the other hand, Isaac, Walker and Williams (1994) find that large groups provide the public good more efficiently than smaller ones. More recently, Zhang and Zhu (2011) reach a similar conclusion by studying the blocking of Chinese Wikipedia in mainland China, which exogenously reduced the group size of

~~Conclusion by studying the blocking of Chinese Wikipedia in mainland China, which exogenously reduced the group size of contributors. Following Andreoni (1989), they use the notion of warm glow (i.e., moral satisfaction from contributing) to explain the inconsistency between the theoretical literature, which predicts that larger groups should free-ride more, and their experimental observations.~~

A key attribute in most of the experimental literature that studies moral hazard in teams is that payoffs are time separable; i.e., in each period agents choose how much to contribute, they receive a compensation that is a function of the total contribution in that period, and they start the next period anew. However, consider building a public park: typically a minimum amount of contribution must be gathered before the public park is built so that it generates utility to the contributors. Georgiadis (2011) develops a theoretical model to study the dynamic collaboration of a team on such a joint project which evolves over time, and it is completed when a pre-specified amount of progress has been accomplished. The main result is that members of a larger team work harder (or equivalently contribute more) than those of a smaller team if and only if the project is sufficiently far from completion.

On the other hand, when the project is close to completion, the total effort of the larger team can become less than that of the smaller team due to excessive free-riding. This result holds both if the project is a public good so that the reward that each agent collects upon completion is independent of the team size, and if the project pays out a fixed reward that is evenly shared among the team members.

The key difference relative to previous models that study teamwork (e.g., Holmstrom (1982), and Bonatti and Horner (2011)) is that contributions are strategic substitutes in these models, while they are strategic complements in Georgiadis (2011). In other words, in Holmstrom (1982) or in Bonatti and Horner (2011), an increase in the contribution by one agent will incentivize others to decrease their own contributions, because each agent views others' efforts as substitutes to their own. On the other hand, in Georgiadis (2011), an increase in the effort level by one agent brings the project closer to completion, thus incentivizing the other agents to also increase their effort levels.

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

In our project, we intend to demonstrate that group size effects in voluntary contribution games play an important, but time-varying role. To study this effect in public good contribution games we employ a novel experimental treatment using continuous time decision-making. All of the interaction between subjects is computer-based, programmed using the standard software z-Tree and will be conducted at CASSEL.

The instructions that we uploaded in Section 10.1 serve as a master protocol and explain in great detail how the experiment will be conducted.

Furthermore, we also included another pdf document that outlines the tested hypothesis in greater detail.

#### 5.0 If applicable, indicate how much time will be required of the subjects, per visit or contact, and in total for the study.

Each experimental session will last approximately 1-2 hours.

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

- Yes - Complete Items 5.1.1 and 5.1.2  
 No  
 Not Applicable

5.1.1 You indicated in Item 5.1 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.

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

- Yes  No

#### 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.

Data is recorded on the computer as the session proceeds. Payment information will be associated with participant's names so that payments can be made once the session is over. Once the session is over, the decision data is stored independently of the identity of the participants. The decision data will be stored on CASSEL servers. Payment information with participant's names is stored securely and separately by CASSEL. No information that links personal information with the data will be used in published research, but it may be used to track participants through several sessions, or to exclude participants based on

participation in past sessions.

ID: IRB#12-000510

View: NEW 11.1 - Characteristics of the Study Population

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

### Characteristics of the Study Population

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

Yes  No

- 2.0 If you answered "no" to item 1.0, indicate the target number of participants to be enrolled under the purview of the PI (the maximum number you hope to enroll):

500

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

1000

- 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 will be recruited from undergraduate and graduate students on campus through the CASSEL website. For some experimental sessions, subjects who are bilingual in English and one other language will be specifically recruited.

- 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.

Sometimes participants are screened to ensure that they have not studied the specific theories being tested, so that their responses will reflect their own thinking rather than the theories they were taught in classes. Restrictions may also be based on participation in previous sessions. In some sessions, we will use only "inexperienced" participants, who have not participated in this type of experiment before. In other sessions, we will draw from the pool of participants who have previously participated. Participation eligibility for "experienced" sessions is not based on the decisions a participant made in earlier sessions. Note that the purpose of "experienced" sessions is to test for the effect of learning. Participation restrictions, which are the exception rather than the rule, are always clearly disclosed during the process of registering on the web for a particular session. The methods of recruiting participants can be expected to generate participant populations that include women and minorities in roughly the same proportions as the UCLA student population.

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

Participation records will be entered into the CASSEL website into a separate, confidential database that is only accessible to CASSEL staff. Eligibility may be determined by prior participation by the use of special filters that are placed on each experiment to exclude subjects that have already participated in the study.

ID: IRB#12-000510

View: NEW 11.2 - Characteristics of Study Population

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

### Characteristics of Study Population

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

Check all that apply:

- 0 to 6 years
- 7 to 11 years
- 12 to 17 years
- 17 or younger in California who can consent for themselves - see note below
- 17 or younger outside California who can consent for themselves - see note below
- 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.**

Adults who are competent to give informed consent

Adults unable to give informed consent

Adults with diminished capacity to consent

Fetal Tissue

Neonates

Participants Unable to Read, Speak, or understand English

Pregnant Women/Fetuses

Prisoners

UCLA Faculty/Staff

UCLA Students

Wards

Unknown/Not Applicable

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

Yes  No

ID: IRB#12-000510

View: NEW 12.6 - UCLA Students or UCLA Faculty/Staff

**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.

**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#12-000510

View: NEW 14.1 - Risks &amp; Benefits

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

## Risks & Benefits

### Benefits

- 1.0 \*Are there any potential direct benefits (physical, psychological, social or other) to study participants?  
 Yes  No

1.1 If yes, describe.

- 2.0 \*Describe the potential benefits to society including the importance of the knowledge to be gained.  
Benefits to society are the generalized knowledge derived from the study described in the description of the purpose of the research. Subjects will not directly benefit from participation in the research.

### 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.

No potential risks or discomforts are known other than risks associated with everyday decision making. Availability of the data does no harm to the participants because the data simply records observed behavior in a decision problem and the identity of the participants is protected.

The overall risk classification is "minimal risk"

### 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:  
Though subjects will not directly benefit from the research there are potential benefits to society as described above. Additionally, there are no discernable risks.

### Alternatives

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

**Check all that apply.**

All types of studies - Choose not to participate in the study

Clinical/Intervention Studies - Receive standard of care instead of participating in the study

Clinical/Intervention Studies - Medication, device, or other treatment is available off study

Item is Not Applicable (e.g., study of existing data)

Other

5.1 If "other" was selected, specify.

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

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

ID: IRB#12-000510

View: NEW 15.1 - Data &amp; Safety Monitoring Plan

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

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

Yes  No

ID: IRB#12-000510

View: NEW 16.1 - Payment for Participation

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

**Payment for Participation****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
- Petty Cash
- Gift Cards/Vouchers
- Non-Monetary Gifts or Services
- Other

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

Deposit in the Bruin Card is optional for larger experimental sessions.

ID: IRB#12-000510

View: NEW 16.2 - Payment for Participation (continued)

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

**Payment for Participation (continued)**

*You indicated that study participants will receive financial or other payment for their participation in the study (item 16.1/item 1.0). Please provide the following information.*

**1.0 \*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.

Monetary rewards based on outcomes, and the anonymity of participants' interactions with one another and the experimenters, serve to ensure that participants are well motivated. This is considered important by economists to maintain experimental control over participants' preferences, which exert a strong influence on the predictions of the theories being tested. Participants are usually paid a small additional amount of \$5-10, for showing up on time and listening to the instructions. The amount of the show-up payment for each session is disclosed on our web site prior to participants registering for a particular session.

Additionally subjects will receive payments based on their decisions. Student's cash earning will be calculated from the total points he or she earns during a specific experiment session. At the conclusion of the experiment, subjects will be paid in cash and in private. Participants will never be in the position of owing money to the experimenter. Other beneficiaries of subjects' decisions can be either other subjects in the experiment, charities, or randomly chosen individuals on the CASSEL subject pool.

ID: IRB#12-000510

View: NEW 16.3 - Costs to Study Participants

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

### Costs to Study Participants

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

Yes  No

**1.1 If yes, describe:**

*The following item pertains to investigational drugs and devices only.*

**2.0 If the study participant or third party payor will be billed for investigational products, attach any documentation to support these charges including FDA letter(s), if available.**

Document Name

Document Version #

There are no items to display

ID: IRB#12-000510

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:**

- |                                     |   |
|-------------------------------------|---|
| <input checked="" type="checkbox"/> | Advertisements/Flyers/Information Sheet/Internet Postings   |
| <input type="checkbox"/>            | 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.) |
| <input type="checkbox"/>            | Random or Other Probability Sampling  |
| <input checked="" type="checkbox"/> | Recruitment letters   |
| <input type="checkbox"/>            | Referrals (e.g., referrals from non-investigator healthcare providers, snowball sampling, participants referring other participants, etc.)  |
| <input type="checkbox"/>            | Review of medical records to identify potential research participants   |
| <input type="checkbox"/>            | Review of publicly available records  |
| <input type="checkbox"/>            | Review of other records   |
| <input checked="" type="checkbox"/> | 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#12-000510

View: NEW 18.2 - Ads/Flyers/Info Sheets/Internet Postings

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

### Ads/Flyers/Info Sheets/Internet Postings

- 1.0 \***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.**

Recruitment of subjects is done through the CASSEL website by drawing on a pool of UCLA students, who have voluntarily registered to become potential subjects. Upon scheduling an experiment session, email announcements with the invitation to participate will be sent randomly (generated by the CASSEL recruiting software) by the CASSEL lab manager, Estela Hopenhayn -who is authorized and qualified to invite subjects participation and answer any inquire regarding the experiment session- at least 3-5 business days in advance to potential subjects registered in the CASSEL database with the time, date and where the experiment session will be held.

- 2.0 **Upload copies of the advertisements/flyers/information sheets/internet postings below. If you will be using announcements on the radio, TV, etc. provide a copy of the script, or a video or audio clip.**

Document Name	Document Version #
There are no items to display	

ID: IRB#12-000510

View: NEW 18.5 - Recruitment Letters

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

### Recruitment Letters

*You have indicated that recruitment letters will be distributed to participants (Section 18.1/item 1.0). Please provide the following information.*

- 1.0 \***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.**

Estela Hopenhayn, lab manager, who is authorized and qualified to invite subjects participation and answer any inquire regarding the experiment session.

- 2.0 **Attach a copy of the letter(s). Include copies of translated forms, if applicable.**

Document Name	Document Version #
New Experiment Announcement2012!.doc	0.01

ID: IRB#12-000510

View: NEW 18.10 - Research Participant Pools/Recruitment Databases

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

### Research Participant Pools/Recruitment Databases

*You have indicated that subjects will be identified and recruited from a subject pool(s) or recruitment database, (Section 18.1/item 1).Please provide the following information.*

- 1.0 \***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.**

CASSEL database, CASSEL/SSGS  
2400 Luskin School of Public Affairs Bldg.

**2.0 If applicable, upload sample scripts and/or recruitment materials:**

Document Name

Document Version #

There are no items to display

ID: IRB#12-000510

View: NEW 19.1 - Eligibility Screening

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."****Eligibility Screening****1.0 \*Will you be conducting a preliminary assessment with potential research participants to determine study eligibility during the recruitment process?** Yes  No

ID: IRB#12-000510

View: NEW 19.2 - Eligibility Screening - Plans

**Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."****Eligibility Screening - Plans**

You indicated that eligibility screening will be conducted during the recruitment process (Section 19.1/item 1). Please provide the following information.

**1.0 \*Will private identifiable information be collected during the screening?** Yes  No**1.1 If private identifiable information is collected during screening, are there plans to retain data from participants found to be ineligible for the study?** Yes  No**1.2 If private identifiable data will be collected during the screening, indicate your plans for retaining the data.** The data will be retained with identifiers The data will be retained without identifiers The data will be destroyed**1.2.1 If you chose more than one response above, explain.****2.0 \*Indicate your plans for obtaining informed consent and/or parental permission for the screening procedures.****Check all that apply.** Oral consent will be obtained for the screening procedures. Participants will not be asked to sign a consent form (Waiver of written consent). A waiver of informed consent is requested for the screening procedures A waiver of Research Authorization for HIPAA is requested for the screening procedures. Signed consent will be obtained prior to performing any of the screening procedures**2.1 If you checked more than one plan above, list the study groups and the plan that you will use for each.**

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

Participants records will be entered into the CASSEL website into a separate, confidential database that is only accessible to CASSEL staff. Eligibility may be determined by prior participation by the use of special filters that are placed on each experiment to ensure new participants for each experiment session.

An announcement is generated by the website and only eligible subjects received the email from CASSEL. When subjects sign up for a particular experiment session if they have already participated a POP OUT with a message (attached in 3.1) is generated by the website, subjects inquire about their ineligibility and the following text is sent by the Lab Manager.

Dear Student,

We are sorry to inform you that you are not eligible to participate in experiment [EXP ID#...] on [date:...] because you have already participated in the same type of experiment [past EXP ID#...] on [Date of participation].

Please try again for coming experiments.

Thank you,  
CASSEL

In 3.1

- 1) Pop out (no eligible)
- 2) Ineligible email from Lab manager

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

Document Name	Document Version #
CASSEL Ineligible Popup Box.pdf	0.01
Eligibility.doc	0.01

ID: IRB#12-000510 View: NEW 19.4 - Request to Waive Informed Consent (and HIPAA Authorization, if applicable) for Screening Procedures

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

### Request to Waive Informed Consent (and HIPAA Authorization, if applicable) for Screening Procedures

*You indicated that you are requesting a waiver of consent (and HIPAA Authorization, if applicable) for Screening Procedures (Section 19.2/item 2).*

**1.0 \*Do the screening procedures pose minimal risk to participants?**

Yes  No

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

Yes  No

**3.0 \*Explain why the research could not practicably be carried out without the waiver of consent or parental permission (or HIPAA Authorization, if applicable) for the screening procedures.**

**Check all that apply.**

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

**3.1 If you indicated that the study design does not allow the possibility of obtaining consent, that requiring consent may introduce systematic bias or checked "other", provide any**

information that may assist the IRB to understand why obtaining consent would not be feasible.

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

**Check all that apply.**

No, the data will not be stored with identifiers with which to contact the participants

No, the information that is found will have no impact on treatment or care

No, there is not a feasible mechanism by which to notify participants/respondents

No, other

Yes

Not Applicable - analysis of secondary data

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

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

ID: IRB#12-000510

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 #

ID: IRB#12-000510

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 appropriate.

**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#12-000510

View: NEW 20.3 - Description of the Consent Process

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

Other

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

There are four stages of informed consent:

- Students register to be in the CASSEL subject pool after reading and acknowledging the generic web consent form

(attached). The consent form contains all elements of informed consents EXCEPT the specific purposes of the research and details about the procedures in specific sessions.

- Students register to be in a specific session by signing up on the web calendar (sample pages attached). The calendar gives pertinent information about specific sessions prior to show-up: it gives the start and end time of the session and the show-up payment.

- After arrival at the laboratory students check in and are reminded that their participation is voluntary and that they are free to leave without penalty.

- After taking their seats they are informed about the specific details of the session through the public reading of a script (sample attached), together with the opportunity to ask questions. The script contains detailed information and instructions about decisions and rules for each part of the session. Listening to the instructions entitles participants to the show-up payment regardless of whether or not they choose to participate in the research session that follows. After the instructions are read, subjects sign a written consent form which reminds them that they are free to leave at any time.

## 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.
- 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.

## Ethics

- Participants are volunteers and they are informed that they are free to leave at any time, without being required to show cause and without penalty. The consent process proceeds through the specific stages above; each stage presents pertinent information and represents a natural stopping point for participants who do not wish to continue.
- The general purpose of the research (to study decision making) is disclosed in the generic web consent form. The specific hypotheses that are being tested in a particular session are not revealed to the participants either before or after the session: We are asking for a waiver of this portion of informed consent. The scientific rationale is discussed below in the section on information withheld from participants.

## Science

- There is no written and signed form. Most elements of

informed consent are present in writing on the generic web consent form, and clicking "accept" constitutes acceptance of the agreement. It is available on the web for participants to review at any time. Similarly the information on the calendar and session registration is written, public, and participants signify their acceptance by clicking the appropriate button to register. In the laboratory the detailed instructions are oral and are reinforced by summaries of pertinent information on the computer screen, on the whiteboard at the front of the room and using LED projectors. Participants indicate their continuing consent through their participation because they are instructed that they are free to leave.

- We do not give participants a written copy of the script, and ask for a waiver of this portion of written informed consent. There are two reasons for presenting detailed instructions orally and through common media such as a whiteboard, but not by distributing individual instruction sheets. First, our goal is to ensure the scientific requirement that participants are both well-informed and equally informed. This creates an environment of common knowledge in which participants know that all other participants are equally cognizant of the rules. Presenting the information publicly rather than privately aids this goal of commonality of understanding. It is important to understand that "common knowledge" plays a crucial role in economic theories because these theories predict that participants' beliefs about other participants' beliefs have an impact on their behavior. Without creating conditions of common knowledge, an important element of experimental control over these beliefs is lost.
- Second, it is important, also for scientific reasons, that as little discussion as possible about the rules take place among the participants. If potential future subjects have had an opportunity to review the rules outside of the laboratory the goal of participants being equally informed is defeated. In addition, by acquiring information (or misinformation) about the rules outside of the laboratory setting, and outside of the experimenter's control, an uncontrolled element is introduced into the experimental data. A particularly serious danger is that if future participants know the details of the rules prior to arriving at the laboratory, they may systematically and intentionally alter their decisions. An example would be an attempt of several students to collude with one another by agreeing beforehand to behave in a certain way. Consequently, we seek to prevent copies of the script from leaving the laboratory and do not inform participants of the rules prior to their arrival at the laboratory. Note that since all subjects are recruited from the UCLA student body, we cannot prevent them from talking to each other. We seek to minimize the lack of experimental control that comes about from these discussions by taking reasonable precautions.

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

Assuring comprehension of the informed consent will occur in three steps. First, participants must read a consent page and give consent to their being in the subject pool. On this web page, students learn about their rights as subjects. Because this page is publicly available on the web, potential participants have ample opportunity to review it before deciding to register for a particular experiment. Second, participants are given pertinent information about the length of the session and the show-up payment when they register for that session on the calendar. Again, the session information is public and potential participants have ample opportunity for review prior to signing up. Third, during the instruction phase of the session, the participants have an opportunity

to ask questions assure their comprehension of the information they have been given. The research session will begin only when participants adequately understand the procedures, the consent process and their rights as subjects.

### 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

Investigator or study team member will evaluate during the consent process

Other --

- 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 #
ScriptEderer	0.01

ID: IRB#12-000510

View: NEW 22.1 - Cultural Considerations

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

**Cultural Considerations**

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

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

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

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

ID: IRB#12-000510

View: NEW 24.0 - Additional Information and/or Attachments

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

**Additional Information and/or Attachments**

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

Document Name	Document Version #
There are no items to display	

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

ID: IRB#12-000510

View: NEW 100.0 - Instructions for Study Submission

**Instructions for Study Submission**

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

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

1. Click the **Finish** button to return to 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#12-000510

View: Other Personnel

**Other Personnel**

**1.0.1 Name, title, institution:**  
Estela Hopenhayn, Lab Manager, CASSEL

**1.0.2 Study role(s): e.g., conduct interviews/surveys, recruit participants, obtain consent, review records, etc.:** Recruiter

ID: IRB#12-000510

View: Display-Collaboration

**None of the options below apply.**

To return to the SmartForm page where you can select the appropriate response, click "OK" below.

View: Chooser

**Name:** IRB#12-000510

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows

**Category Description:**

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:  
 (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 mL in an 8 week period and collection may not occur more frequently than 2 times per week; or  
 (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 mL or 3 mL per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

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

ID: IRB#12-000510

View: Chooser

**Name:**

(3) Prospective collection of biological specimens for research purposes by non-invasive means

**Category Description:**

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

**Examples:**

- (a) hair and nail clippings in a nondisfiguring manner;
- (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- (c) permanent teeth if routine patient care indicates a need for extraction;
- (d) excreta and external secretions (including sweat);
- (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
- (f) placenta removed at delivery;

(g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor.

- (g) amniotic fluid obtained at the time of rupture or the membrane prior to or during labor;
- (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
- (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- (j) sputum collected after saline mist nebulization.

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

**ID:** IRB#12-000510

[View: Chooser](#)

**Name:**

(4) Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves

**Category Description:**

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

**Examples:**

- (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy;
- (b) weighing or testing sensory acuity;
- (c) magnetic resonance imaging;
- (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
- (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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

**ID:** IRB#12-000510

[View: Chooser](#)

**Name:**

(5) Research involving materials (data, document, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes

**Category Description:**

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

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

**ID:** IRB#12-000510

[View: Chooser](#)

**Name:**

(6) Collection of data from voice, video, digital, or image recordings made for research purposes

**Category Description:**

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

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

**ID:** IRB#12-000510

[View: Chooser](#)

**Name:**

(7) Research on individual or group characteristics or behavior

**Category Description:**

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

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

**ID:** IRB#12-000510

[View: Chooser](#)

**Name:**

(1) Clinical studies of drugs and devices only when condition (a) or (b) is met

**Category Description:**

- (1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
- (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
- (b) Research on medical devices for which
- (i) an investigational device exemption application (21 CFR Part 812) is not required; or
  - (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

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

**ID:** IRB#12-000510

View: Chooser

**Name:**

(8) Research which was previously reviewed by the convened IRB, but meets the criteria for Expedited review and meets one of the following categories for Expedited review as defined by OHRP and the FDA

**Category Description:**

(8) Research which was previously reviewed by the convened IRB, but meets the criteria for Expedited review and meets one of the following categories for Expedited review as defined by OHRP and the FDA: (a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) Where no subjects have been enrolled and no additional risks have been identified; or (c) Where the remaining research activities are limited to data analysis.

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

**ID:** IRB#12-000510

View: Chooser

**Name:**

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply

**Category Description:**

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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

**ID:** IRB#12-000510

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#12-000510

View: Display - Method Description

Behavioral Observations (only applicable if you selected Exempt Category 2 in section 5.3)

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

**ID:** IRB#12-000510

View: Display - Method Description

Certificate of Confidentiality

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. The project does not need to be funded by NIH to obtain a Certificate of Confidentiality. For additional information see <http://grants.nih.gov/grants/policy/coc/>

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

ID: IRB#12-000510

View: Display - Method Description

#### Clinical Trial of a Behavioral Intervention (if applicable, select additional related categories)

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#12-000510

View: Display - Method Description

#### Clinical Trial of a Drug, Biologic or Device (You must also specify below "Device/Diagnostics" and/or "Drugs/Biologics/Dietary Supplements")

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#12-000510

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#12-000510

View: Display - Method Description

#### Drugs/Biologics/Dietary Supplements

o 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.  
o 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>  
o 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#12-000510

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), methylenedioxymethamphetamine (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#12-000510

[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#12-000510

[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#12-000510

[View: Display - Method Description](#)

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

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

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

**ID:** IRB#12-000510

[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#12-000510

[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.

<https://webirb.research.ucla.edu/WebIRB/ResourceAdministration/Project/PrintSmartForms?Project=co...>

**Infectious Agents**

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

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

**ID:** IRB#12-000510                                  View: Display - Method Description

Radiation (Standard of Care or Investigational use of radioactive materials or ionizing radiation)

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

**ID:** IRB#12-000510                                  View: Display - Method Description

Substance Abuse Research (with Medication)

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

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

**ID:** IRB#12-000510                                  View: Display - Method Description

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

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

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

**ID:** IRB#12-000510                                  View: Display - Method Description

**None of the above**

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