PROTOCOL
Soc-Behav-Ed Non-Exempt
Berkeley

Protocol # 2014-03-6134
Date Printed: 08/26/2014

Protocol Title:	Towards the New Making Renaissance: Tools for Creative Making
Protocol Type:	Soc-Behav-Ed Non-Exempt
Date Submitted:	08/22/2014
Approval Period:	Draft
Important Note:	**This Print View may not reflect all comments and contingencies for approval. Please check the comments section of the online protocol. Questions that appear to not have been answered may not have been required for this submission. Please see the system application for more details.**

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* * * Amendment Application * * *

Amendment Application

1. **Summarize the amendment (or proposed changes) you wish to make to your study.**

A. For the screening survey, we would like to include a few demographics question (age, gender).
B. Method of payment - At the workshop research study, we will instead be requesting the users email to send out a link for a $X Visa Gift Card ($20p/hr) to the participant.
C. Adding a followup phone interview.

2. **Explain the reason(s) for the proposed amendment(s).**

A. We are also changing the criteria for inclusion to have a balanced gender ratio to have a diverse set of participants.
B. A logistical issue on payment. This is the standard method for user-study payment within the EECS department.

C. A portion of the study wishes to address how people interact with their designed objects after the workshop (what they do with them, where they put them, why they put them there, stories associated with the object, how do they introduce it to people). We will collect address information to ship the fabricated object, or make the object available for pickup. A week after the object has been received, we will followup with a 5-10min phone interview, for which the user will be compensated $5.

3. **Indicate how the change(s) impact the level of risk to subjects:**

	Increase
Y	**No Change**
	Decrease

4. **Describe any effects the change(s) will have regarding risk(s) to the subjects:**

No changes in risk to subjects.

5. **Will this amendment require the re-consent of any currently enrolled subjects?** **N**

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If YES, please explain.

6. Is this modification consistent with the scope of research activities as described in the proposal(s) for the grant(s) funding the research? (Check N/A if you have no external funding) Y

7. Proceed to the appropriate section(s) and make your changes. The list of sections that have been changed or modified will appear below:

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* * * Personnel Information * * *

Enter all UC Berkeley study personnel (if not previously entered) and relevant training information. Please read Personnel Titles and Responsibilities: Roles in eProtocol before completing this section.

Note: The Principal Investigator or Faculty Sponsor, Co-Principal Investigator, Student or Postdoctoral Investigator, Administrative Contact, and Other Contact can EDIT and SUBMIT. Other Personnel can only VIEW the protocol.

Principal Investigator or Faculty Sponsor

Name of Principal Investigator	Degree (e.g., MS/PhD)	Title
Eric Paulos	PhD	Assistant Professor
Email	**Phone**	**Fax**
paulos@berkeley.edu		
Department Name	**Mailing Address**	
Computer Science	464 Sutardja Dai Hall, UC Berkeley	

UCB status (select all that apply):

X	Faculty		Postdoc		Grad		Undergrad		Other

ALL PIs and KEY PERSONNEL on an NIH award are required to complete NIH Training or an accepted equivalent. ALL STUDENTS engaged in human subjects research are required to complete CITI training. See Training and Education for more information.

If applicable, please insert date (mm/dd/yy) of completion in appropriate box(es) below:

CITI	NIH	Other Training (title & date completed)

Student or Postdoctoral Investigator

NOTE: All Student/Postdoc Investigators must have a Faculty Sponsor who will serve as the "responsible researcher." If NOT a student or postdoc project, enter student(s) and/ or postdoc(s) under Other Personnel below.

Name of Student/Postdoc Investigator	Degree	Title
CESAR ARMANDO JR TORRES	BA/BS	

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TORRES

Email	Phone	Fax
cearto@berkeley.edu	9152084709	

Department Name	Mailing Address
Computer Science	464 Sutardja Dai Hall, UC Berkeley

UCB status (select all that apply):

	Faculty		Postdoc	X	Grad		Undergrad		Other	

ALL PIs and KEY PERSONNEL on an NIH award are required to complete NIH Training or an accepted equivalent. ALL STUDENTS engaged in human subjects research are required to complete CITI training. See Training and Education for more information.

If applicable, please insert date (mm/dd/yy) of completion in appropriate box(es) below:

CITI	NIH	Other Training (title & date completed)

Administrative Contact

Name of Administrative Contact	Degree	Title
Anthony Stamos		Research Administrator IV

Email	Phone	Fax
astamos@berkeley.edu	+1 510 643-2568	

Department Name	Mailing Address
Campus Shared Services	94720-1776

UCB status (select all that apply):

	Faculty		Postdoc		Grad		Undergrad		Other	

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* * * Vulnerable Subject Checklist * * *

Vulnerable Subject Checklist

Yes	No	
	N	Children/Minors
	N	Prisoners
	N	Pregnant Women
	N	Fetuses
	N	Neonates
	N	Educationally Disadvantaged
	N	Economically Disadvantaged
	N	Cognitively Impaired
	N	Other (i.e., any vulnerable subject population(s) not specified above)

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* * * Study Sites * * *

Study Sites

Select All That Apply :

International

International Site(s) (specify country, region, and township or village)

Local

X UC Berkeley

UC Davis

UC Irvine

UC Los Angeles

UC Merced

UC Riverside

UC San Diego

UC San Francisco

UC Santa Barbara

UC Santa Cruz

Lawrence Berkeley National Laboratory

Alameda Unified School District (specify schools below)

Berkeley Unified School District (specify schools below)

Oakland Unified School District (specify schools below)

Other (Specify other Study Sites)

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* * * General Checklist * * *

General Checklist

Yes	No	
Y		Is the research receiving any federal funding (e.g., NIH, NSF, DOD, etc.)
	N	Is another UC campus relying on UC Berkeley for IRB review by means of the UC System Memorandum of Understanding (MOU)?
	N	Is another institution relying on UC Berkeley for IRB review by means of an Inter-institutional IRB Authorization Agreement?
Y		Will subjects be paid for participation?
	N	Is this protocol administratively supported by Research Enterprise Services (RES)?

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* * * Funding * * *

Funding Checklist

If the research is not funded, check the "Not Funded" box below. If the research is funded, add the funding source to the appropriate table below.

NOTE: Only the Principal Investigator (PI) of the grant or subcontract can add his or her own SPO Funding information in this section. The PI of the grant must also be listed in the Personnel Information section of the protocol in one of the following roles: Principal Investigator or Faculty Sponsor, Student or Postdoctoral Investigator, Co-Principal Investigator, Administrative Contact, or Other Contact. Training Grants can be added by anyone in one of the aforementioned roles. For step-by-step instructions, see Add SPO Funding Quick Guide

Not Funded

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* * * Expedited Paragraphs * * *

Request for Expedited Review

An expedited review procedure consists of a review of research involving human subjects by the IRB Chair, or by one or more experienced reviewers designated by the Chairperson from among the members of the committees.

In order to be eligible for expedited review, ALL aspects of the research must include activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures included in one or more of the specific categories listed below.

If requesting Expedited Review, select one or more of the applicable paragraph(s) below.
(DO NOT select any paragraph(s) if your protocol does not qualify for expedited review. Protocols that do not qualify for expedited review will be reviewed by the full (convened) Committee.)

1. Clinical studies of drugs and medical devices only when conditions (a) and (b) are 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.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

   a) From healthy, non-pregnant 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

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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.

3. **Prospective collection of biological specimen for research purposes by non-invasive means.**

   Examples:

   a) hair and nail clippings in a non-disfiguring 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;
   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
   j) sputum collected after saline mist nebulization.

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. 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 of 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.

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5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this paragraph 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.)

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

X 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.)

8. Continuing review of research previously approved by the convened IRB as follows:

   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.

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.

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* * * Purpose, Background, Collaborative Research * * *

Old CPHS # (for Protocols approved before eProtocol)

Study Title

Towards the New Making Renaissance: Tools for Creative Making

Complete each section. When a question is not applicable, enter "N/A". Do not leave any sections blank.

1. Purpose

Provide a brief explanation of the proposed research, including specific study hypothesis, objectives, and rationale.

1. Research Objective

The purpose of our study is to evaluate new software tools for making digital fabricated objects. We have developed a CAD modeling tools that use existing 3D models and allows users to modify them in new and interesting ways. In particular, we incorporate chance and environmental variables into our software. We want to discover how this might change the making process to potentially make object more more expressive, adaptable, dynamic, and authentic.

2. Research Hypothesis
We expect that participants will feel more artistic agency when manipulating objects using our CAD software, and anticipate that our parametric approach will inspire a new subset of designs, while our deterministic approach will be the most approachable and similar to existing techniques.

2. Background

Give relevant background (e.g., summarize previous/current related studies) on condition, procedure, product, etc. under investigation, including citations if applicable (attach bibliography in Attachments section).

Experimental approach:
We will be evaluating software for computational design for digital fabrication application.

Studies in this area have particularly investigated how to engage novice programmers in computational design [1]. Jacobs & Buechley develop a programming tool for computational design for artifacts that will later be digitally manufactured to produce personal and functional objects. This tool was evaluated in a one-day preliminary workshop in which participants design and build lamps, as well as pre and post-surveys and interviews (15-30 minutes with recorded and transcribed audio). Participants altered code

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representations of lamps, and were then asked to produced lamps using digital fabrication tools such as a laser cutter.

The study also investigated a longer term workshop evaluation, although we model our approach on solely the preliminary study.

Differences in our approach: 1) we will be conducting a shorter workshop (2 hours) and 2) participants will not be using the digital fabrication tools, and only creating a digital model, 3) participants will receive their fabricated after the workshop has concluded and be followed up with a phone interview.

3. Collaborative Research

a) **If any non-UCB institutions or individuals are engaged in the research, explain here.**

N/A

b) **If any non-UCB institutions or individuals are collaborating in the research, complete the table below and attach any relevant IRB approvals in the Attachments section.**

4. Qualifications of Study Personnel

a) **Explain expertise of Principal Investigator, Student/Postdoc Investigator, Faculty Sponsor (if applicable), any Co-Investigators or other key personnel listed in the application, and how it relates to their specific roles in the study team.**

Student investigator has conducted a psychophysics human subjects test and is familiar with IRB procedures.
Principal investigator is a Associate Professor of Computer Science and will be overseeing the study.

b) **In case of International research, describe the expertise you have, or have access to, which prepares you to conduct research in this location and/or with this subject population, including specific qualifications (e.g., relevant coursework, background, experience, training). Also, explain your knowledge of local community attitudes and cultural norms, and cultural sensitivities necessary to carry out the research. See CPHS Guidelines on Research in an International Setting**

N/A

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* * * Subject Population * * *

5. Subject Population

a) Describe proposed subject population, stating age range, gender, race, ethnicity, language and literacy.

Participants must be older than 18 years old and be computer literate.

b) State total (maximum) number of subjects planned for the study and how many must be recruited to obtain this sample size. Explain how number of subjects needed to answer the research question was determined.

We anticipate a maximum of twelve participants will need to be recruited, and will screen participants with a survey. In particular we are looking for a uniformly distributed design expertise from participants (traditional, digital, and Industrial). In the related literature, workshop sizes are between 8-12 participants.

c) If any proposed subjects are children/minors, prisoners, pregnant women, those with physical or cognitive impairments, or others who are considered vulnerable to coercion or undue influence, state rationale for their involvement.

N/A

6. Recruitment

a) Explain how, where, when, and by whom prospective subjects will be identified/selected and approached for study participation. If researcher is subject's instructor, physician, or job supervisor, or if vulnerable subject groups will be recruited, explain what precautions will be taken to minimize potential coercion or undue influence to participate. See CPHS Guidelines on Recruitment for more information.

Participants will be recruited from the Berkeley area using campus mailing lists and Craigslist ads. Selection criteria will be based on different experience levels of design. If researcher is subject's instructor, we will follow CPHS guidelines. We will send out a general call for participation using campus mailing lists and allow interested persons to initiate contact, and a neutral third party will obtain consent.

The email will be sent by a third-party who has routine access to the mailing lists.

b) Describe any recruitment materials (e.g., letters, flyers, advertisements [note type of media/where posted], scripts for verbal recruitment, etc.) and letter of permission/cooperation from institutions, agencies or organizations where off-site subject recruitment will take place (e.g., another UC campus, clinic, school district). Attach these documents in Attachments section.

We will be recruiting using a SF bay Craigslist ad on the design jobs column, as well as a recruitment

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email sent on the general design, architecture, and computer science mailing lists at UC Berkeley.

Email and Ad Recruitment Email in attachments.

c) **Will anyone who will be recruiting or enrolling human subjects for this research receive compensation for each subject enrolled into this protocol? If yes, please identify the individual(s) and the amount of payment (per subject and total).**

No.

7. Screening

a) **Provide criteria for subject inclusion and exclusion. If any inclusion/exclusion criteria are based on gender, race, or ethnicity, explain rationale for restrictions.**

In particular we are looking for different design expertise amongst participants (traditional [3], digital[4], and modeling[5]). We will fill a quota for each expertise level (~3-4 for each level). Participants will be chosen based on the self-reported experience from the screening survey. In the screening survey, users that self-reported expertise of 5 or greater for questions 2a (traditional), 3a(digital), and 4a(industrial) will be considered if the quota corresponding to each question has been filled.

For example, a participant reports in the screening survey a value greater than 5 for Question 3a. This would place the participant as having digital expertise and in the digital group. If the quota of 3 participants for the digital group has not been reached, then the participant will be invited to take place in the study.

Participants that report more than one expertise area will be placed in the group with the lowest filled quota.

We will also be looking for a equal distribution of gender within each expertise level. At least a single person from each gender will be represented in each expertise group.

b) **If prospective subjects will be screened via tests, interviews, etc., prior to entry into the "main" study, explain how, where, when, and by whom screening will be done. NOTE: Consent must be obtained for screening procedures as well as "main" study procedures. As appropriate, either: 1) create a separate "Screening Consent Form;" or 2) include screening information within the consent form for the main study.**

Document added "Screening Survey", questionnaire of experience with creative tools.
We will be sending a call for participation through email and Craigslist ads.

This call will have a link to a SurveyMonkey secure survey tool, accessible only to the investigators, containing the questions from the Screening Survey. The participant's email address will be collected through the SurveyMonkey survey and be used to link responses from the survey.

This record will be deleted one month after the end of the study.

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8. Compensation and Costs

a)

Describe plan for compensation of subjects. If no compensation will be provided, this should be stated. If subjects will be compensated for their participation, explain in detail about the amount and methods/ terms of payment.

Include any provisions for partial payment if subject withdraws before study is complete.

When subjects are required to provide Social Security Number in order to be paid, this data must be collected separately from consent documentation. If applicable, describe security measures that will be used to protect subject confidentiality.

If non-monetary compensation (e.g., course credit, services) will be offered, explain how

Non-monetary compensation will not be offered.

b) Discuss reasoning behind amount/method/terms of compensation, including appropriateness of compensation for the study population and avoiding undue influence to participate.

The study consists of a 2 hour workshop and a followup phone interview. Applicants will be compensated $40 for participating in the workshop. The average wage for design work on oDesk crowdsourcing platform is about $15-20 per hour. Workshop payment will be $20/hr and the followup phone interview will be $5 for 5-10min.

Workshop
If a participant chooses to withdraw from the study, they will be prorated compensation at $20/hr. Payment will occur upon withdrawal. Payment will be $20 Visa gift card(s). A link to a digital Visa gift card will be emailed to the participant at the conclusion of the study.

Followup phone-interview
Since the phone-interview is short (5-10min), compensation will not be prorated should the participant chose to withdraw from the interview. Payment will be $5 Visa gift card(s). A link to a digital Visa gift card will be emailed to the participant at the conclusion of the phone interview.

c) Costs to Subjects. If applicable, describe any costs/charges which subjects or their insurance carriers will be expected to pay. (If there are no costs to subjects or their insurers, this should be stated.)

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There are no costs to subjects or their insurers.

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* * * Study Procedures, Alternatives to Participation * * *

9. Study Procedures

a) Describe in chronological order of events how the research will be conducted, providing information about all study procedures (e.g., all interventions/interactions with subjects, data collection procedures etc.), including follow-up procedures.

Research Study Agenda

Experiment - Pre-Study Paperwork
Participants will first be assigned a participant identification number to be used throughout the study. Participants will then be guided through the informed consent form.

Experiment - Workshop (135-140 min)

Tutorial (15 min)
Participants will be using custom built software on a desktop computer provided by the investigators. The investigators will begin by presenting on a large screen an overview of different interface features, and then present examples of how each interface feature can be used to alter an existing 3D model.

Warmup modelling task (20 min)
A participant will be asked to replicate the example interactions presented during the tutorial. Investigators will be answering any questions that arise during this time.

Design Activity (80 min)
Once familiar, participants will be assigned three design prompts conditioned on features of our software e.g. "Alter a 3D model using parametric sliders." Participants will have the choice of looking through a repository of ~400 3D models of objects, animals, and humans and choosing which model to alter.

Interview (15min)
The workshop will conclude with a 15 minute interview where the participant will be audio recorded for transcription purposes. Interview questions are provided in "IRB InterviewQuestions.pdf".

Followup Interview (5-10min)
One of the user's created designs from the workshop will be fabricated and shipped to the user (or be available for pick up). One week after the participant has received the object, we will followup with a 5-10 minute phone interview. Followup interview questions are provided in "Followup IRB InterviewQuestions.pdf".

b) Explain who will conduct the procedures, where and when they will take place. Indicate frequency and duration of visits/sessions, as well as total time commitment for the study.

The workshop will take place in Sutardja Dai Hall in the Invention Studio and will conducted by Cesar

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Torres. The followup interview will occur via telephone.

Total Time Commitment: ~2hrs

c) Identify any research procedures that are experimental/investigational. Experimental or investigational procedures are treatments or interventions that do not conform to commonly accepted clinical or research practice as may occur in medical, psychological, or educational settings. Note: if the study only involves standard research or clinical procedures, enter "N/A" here.

N/A

d) If any type of deception or incomplete disclosure will be used, explain what it will entail, why it is justified, and what the plans are to debrief subjects. See CPHS Guidelines on Deception and Incomplete Disclosure for more information. Any debriefing materials should be included in the Attachments section.

N/A

e) State if audio or video recording will occur and for what purpose (e.g. transcription, coding facial expressions).

Audio and phone conversations will be recorded for transcribing into notes. Audio will be deleted a month after conclusion of the study.

10. Alternatives to Participation

Describe appropriate alternative resources, procedures, courses of treatment, if any, that are available to prospective subjects. If there are no appropriate alternatives to study participation, this should be stated. If the study does not involve treatment/intervention, enter "N/A" here.

N/A

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* * * Risks and Discomforts * * *

11. Risks and Discomforts

a) **Describe all known risks and discomforts associated with study procedures, whether physical, psychological, economic or social (e.g., pain, stress, invasion of privacy, breach of confidentiality), noting the likelihood and degree of potential harm.**

Participant Safety

No forseeable harm is anticipated with this study. Participants will be interacting with a standard desktop computer. Some stress and fatigue might occur, but none that would not other be experienced by normal desktop environments. Fabrication will be handled by the investigators.

b) **Discuss measures that will be taken to minimize risks and discomforts to subjects.**

Comptuer mice, keyboards, and large displays will be provided to reduce fatigue.

c) **Discuss plans for reporting unanticipated problems involving risks to subjects or others, or serious adverse events, to CPHS. (This applies to all types of research.) See Adverse Event and Unanticipated Problem Reporting.**

In case of unanticipated problems, participants will be asked to stop the study. An initial report will be sent by email to the Director, Research Subject Protection as soon as possible, but within no more than one week (7 calendar days) of the Principal Investigator learning of the incident. A formal written report will be written within no more than two weeks (14 calendar days) of the Principal Investigator learning of the incident.

d) **Describe plans for provision of treatment for study-related injuries, and how costs of injury treatment will be covered. If the study involves more than minimal risk, indicate that the researchers are familiar with and will follow University of California policy in this regard, and will use recommended wording on any consent forms (see CPHS Informed Consent Guidelines).**

The study involves minimal risk.

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* * * Benefits, Confidentiality * * *

12. Benefits

Describe any potential benefits to the individual subject, group of subjects, and/or society. If subjects will not benefit directly from study procedures, this should be stated.

NOTE: Do not include compensation/payment of subjects in this section, as remuneration is not considered a "benefit" of participation in research.

Information gathered from this study will go to benefit future designs of computational design tools, which will allow a greater population to interact with digital fabrication tools and broaden participation outside of solely the sciences.

13. Confidentiality and Privacy

NOTE: See CPHS Data Security Policy and Guidelines before completing this section.

a) What identifiable data will you obtain from participants? Note: Audio, photo, and video recordings are generally considered identifiable unless distinguishing features can be successfully masked.

A person's participation with our study is not expected to lead to any damage to reputation or standing within the community.

Collected identifiable data includes:
a) screening survey : email address
b) workshop: email address, audio recordings, mailing address, phone number

b) If obtaining existing data/specimens, will you have access to identifiers?

No.

c) Explain how the confidentiality of subject information will be maintained. Include:

i. Who will have access to study records/specimens?

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Only this study's investigators will be allowed access to the study records.

ii. How the records will be secured (e.g., password-protected computer, encrypted files, locked cabinet). Response should be consistent with CPHS Data Security Policy.

The data will be collected with a key-value system. A single physical document (key) will link the research data to your identifiable information

Research records, including audio recording and computer-based data, will be stored in a locked cabinet (physical materials), in a secured building and/or in an encrypted, on a password-protected computer (digital materials).

iii. How long study data will be retained.

For the screening survey, data will be destroyed immediately should the participants not be selected for the study. Personal identifiers (email addresses, phone number, mailing address, key) will be destroyed a month after the end of this study. Main research study data will be retained up to five years after the conclusion of the study.

iv. When audio/video recordings will be transcribed and when they will be destroyed (if ever).

Audio recordings will be transcribed within a month of the main research study and destroyed immediately thereafter.

d) Identifiers should be removed from data/specimens as soon as possible following collection, except in cases where the identifiers are embedded (e.g., voices in audio or faces in video recordings). If data are coded in order to retain a link between the data and identifiable information, explain where the key to the code will be stored, how it will be protected, who will have access to it, and when it will be destroyed.

N/A

e) Describe how identifiable data will be transferred (e.g., courier, mail) or transmitted (e.g., file transfer software, file sharing, email). If transmitted via electronic networks, describe how you will secure the data while in transit (e.g., prior encryption). If not applicable, enter N/A.

Screening data is collected and SSL/TLS encrypted through SurveyMonkey, a third-party online survey software.

Email correspondence will be encrypted prior to transmission.

f) Will subjects be asked to give permission for release of identifiable data (e.g., for publications or presentations), now or in the future? If so, explain here and include appropriate statements in the consent

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presentations), now or in the future? If so, explain here and include appropriate statements in the consent materials. See Media Records Release Form template for guidance.

Subjects will not be asked to give permission for release of identifiable data.

g) Explain how subject privacy will be protected (e.g., conducting interviews in a discreet location).

The research workshop will be conducted in a private conference room with only the researcher(s) and at most two other participants. Interviews will be conducted one-on-one with a researcher in a separate room. All other interviews will be conducted via telephone.

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* * * Potential Financial Conflict of Interest * * *

14. Potential Financial Conflict of Interest

Individuals who have independent roles in projects and who are responsible for the design, analysis, conduct, or reporting of the results of research performed (or to be performed) under a human subjects protocol must disclose whether or not they have a financial interest in or association with the sponsor or the company supplying materials, drugs, or devices for the project. This checklist pertains to the entire project team working under the protocol. Any individual who has a conflict must comply with University regulations and procedures for disclosure of financial conflict of interest.

See Conflict of Interest Committee Website for more information.

Please answer the following questions:

Does any member of the project team (defined as UCB or non-UCB personnel working under the protocol) with substantive responsibility for the design, conduct, or reporting of activities under the protocol, or any member of their immediate family (defined as spouse, dependent child, or registered domestic partner) have any of the following relationships with the non-UC entity financing the research to be done under the protocol or the non-UC entity supplying materials, drugs or devices being tested under the protocol:

1. N **Positions of management (e.g., board member, scientific advisor, director, officer, partner, trustee, employee, consultant).**
2. N **Equity interest (e.g., stock, stock options, investment, or other ownership).**
3. N **Rights to a pending patent application or issued patent to any invention(s), or license rights or copyright for software that has a direct relationship to the project proposed.**

If the answer to any of the above is Yes, then each individual with any "Yes" response(s) must submit a Human Subjects Financial Conflict of Interest Form DIRECTLY to the Conflict of Interest (COI) Committee for a separate review.

NOTE: When review by the COI Committee is required, CPHS approval or exemption of protocols will be contingent upon the disclosure and resolution of all financial conflicts of interest, as determined by the COI Committee.

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* * * Informed Consent * * *

15. Informed Consent

Add the consent documents and/or waivers needed for this research using the table at the bottom of the page. Any foreign language versions should also be added. You will be asked to provide relevant background information for each consent document or waiver. The various consent/waiver options are described below.

Note: DO NOT include child assent documents, parent permission documents or waivers here (these are addressed in the next section).

Altered and Unsigned Consent - A consent document that has omitted required information and does not include a place for a participant's signature. This means that CPHS is being asked to waive one or more elements of consent in addition to the requirement for documented consent.

Altered Consent Form - A consent form that has omitted required information. This means that the CPHS is asked to waive one or more required elements of informed consent. For example, if the purpose of the study will not be disclosed to participants in order to avoid bias, this option should be selected because disclosure of the "purpose" is a required element of informed consent. The form must include a signature line and date line for the individual to sign if he or she agrees to participate.

Consent Form - A standard consent document that embodies all of the required information (elements of informed consent) designed to help an individual make an informed decision about whether or not to participate in the research. The form must include a signature line and date line for the individual to sign if he or she agrees to participate. The Consent Form can also be presented as a "short form" document stating that the required elements of informed consent have been presented orally to the participant. When the short form method is used, a "summary" of the information that is presented to the participant must also be provided for CPHS approval and there must be an impartial witness to the oral presentation. The witness must sign the summary as well as the short form and the participant must sign the summary. The "short form" method may be used in circumstances where oral presentation of consent is preferable or necessary, e.g., subjects are illiterate in English or their native language.

Consent Waiver - No consent will be sought at all. This means that the CPHS is asked to waive the requirement for informed consent. This option is often appropriate for research that involves use of existing data or samples

Unsigned Consent - A document that embodies all of the required information (elements of informed consent), but does not include a place for a participant to indicate with a signature that he or she agrees to take part in the research. This means that the CPHS is asked to waive the requirement for documented (signed) consent. For example, if consent will be obtained verbally or using a button on the web, this option

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should be selected.

•Informed Consent Guidelines, Templates and Sample Forms

•Informed Consent Policies and Procedures

•Consent Builder: Online Tool for Creating Consent Forms

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* * * Child Assent & Parent Permission * * *

16. Child Assent and Parent/Guardian Permission

Add each assent document, parent/guardian permission document, and/or waiver needed for this research using the table at the bottom of the page. Any foreign language versions should also be added. You will be asked to provide relevant background information for each assent, permission, or waiver. The various assent, permission, and waiver options are described below.

Altered and Unsigned Parent/Guardian Permission Form - A parent permission document that has omitted required information (elements) and does not include a place for a parent to indicate with a signature that he or she agrees to permit the child's participation. This means that CPHS is being asked to waive one or more elements of consent in addition to the requirement for documented consent.

Altered Parent/Guardian Permission Form - A permission form that has omitted required information (elements). This means that the CPHS is asked to waive one or more required elements of informed consent. However, the form must include signature and date lines for the parent(s)/guardian(s) to sign if the child is permitted to take part in the research.

Assent Document - A form or script of the information that will be conveyed to the child about the study. In general, researchers must obtain the affirmative agreement of children ages seven years and older for their participation. Assent forms should be written at a level understandable to the child. If the study includes a broad age range of children, more than one assent form may be needed (i.e., an assent form suitable for a 15 year old is not usually suitable for a 7 year old child).

Assent Waiver - No child assent will be sought at all. This means that CPHS is asked to waive the requirement for child assent. Among other circumstances, this option is appropriate when the capability of the child to understand the research is too limited or when the research holds out a prospect of direct benefit that is important to the health or well being of the child.

Parent/Guardian Permission Form - A document that embodies all of the required information (elements of informed consent) designed to help the parent/guardian of a child make an informed decision about whether or not to permit the child's participation in the research. The form must include signature and date lines for the parent(s)/guardian(s) to sign if the child is permitted to take part in the research.

Permission Waiver - No parent/guardian permission will be sought at all. This means that the CPHS is asked to waive the requirement for parent/guardian permission. This option, for example, is often appropriate for research designed to study conditions in children or a study population for which parental

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appropriate for research designed to study conditions in children or a study population for which parental permission is not a reasonable requirement to protect the children (e.g., neglected or abused children).

Unsigned Parent/Guardian Permission Form - A parent permission document that embodies all of the required information (elements of informed consent), but does not include a place for a parent to indicate with a signature that he or she agrees to permit the child's participation. This means that the CPHS is asked to waive the requirement for documented (signed) consent.

- **Child Assent and Parent Permission Guidelines, Templates, and Sample Forms**

•Policies and Procedures on Child Assent and Parent Permission

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* * * Attachments * * *

17. Attachments

Add appropriate attachments (e.g., advertisements, data collection instruments, IRB approvals from collaborating institutions, etc.) in this section. Attachments MUST be in PDF format.

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* * * Assurance * * *

Assurance

As Faculty Sponsor, I understand that I am responsible for overseeing the protection of the rights and welfare of the human subjects, and adherence to CPHS requirements, federal regulations, and state statutes for human subjects research.

I hereby assure the following:

1. I have read the protocol.
2. I have discussed with the Student/Postdoc Investigator how to comply with his or her assurances.
3. I will be available throughout the course of the study to provide guidance and consultation.

X **I have read and agree to the above assurances.**

As Student/Postdoctoral Investigator, I am responsible for the performance of this study, the protection of the rights and welfare of the human subjects, and strict adherence by all co-investigators and research personnel to CPHS requirements, federal regulations, and state statutes for human subjects research.

I hereby assure the following:

1. The information provided in this application is accurate to the best of my knowledge.
2. All experiments and procedures involving human subjects will be performed under my supervision or that of another qualified professional listed on this protocol.
3. This protocol covers the human subjects research activities described in the grant proposal(s) supporting this research and any such activities that are not covered have been/will be covered by a

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CPHS approved protocol.

4. The legally effective informed consent of all human subjects or their legally authorized representative will be obtained (unless waived) using only the current, approved consent form(s).

5. If any study subject experiences an unanticipated problem involving risks to subjects or others, and/or a serious adverse event, the CPHS will be informed promptly within no more than one week (7 calendar days), and receive a written report within no more than two weeks (14 calendar days), of recognition/ notification of the event.

6. No change in the design, conduct, or key personnel of this research will be implemented without prior CPHS review and approval, unless the changes are necessary to eliminate an apparent immediate hazard to subjects. Changes made to eliminate hazards to subjects will be reported to OPHS/CPHS via the AE/UP reporting process.

7. Applications for continuation review will be submitted in a timely manner prior to the expiration date to allow sufficient time for the renewal process. I understand that if approval expires, all research activity (including data analysis) must cease until I receive notice of re-approval by the CPHS.

8. Participants' complaints or requests for information about the study will be addressed appropriately.

9. I will promptly and completely comply with a CPHS decision to suspend or withdraw its approval for the project.

10. I will submit a study closure form at the conclusion of this project.

X **I have read and agree to the above assurances.**
