PROTOCOL
Soc-Behav-Ed Non-Exempt
Berkeley

Protocol # 2010-02-881
Date Printed: 11/24/2013

Protocol Title:	Visual-Haptic-Auditory Integration
Protocol Type:	Soc-Behav-Ed Non-Exempt
Date Submitted:	01/22/2013
Approval Period:	03/20/2013-03/19/2014
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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
Martin S BANKS	PhD	Prof
Email	**Phone**	**Fax**
martybanks@berkeley.edu	+1 510 642-7679	
Department Name	**Mailing Address**	
OPTM-Vision Sci	94720-2020	

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)

Administrative Contact

Name of Administrative Contact	Degree	Title
Peter ILLES		Lab Manager
Email	**Phone**	**Fax**

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peter.illes@berkeley.edu +1 510 642-7679 +1 510 643-5109

Department Name **Mailing Address**
OPTM-Vision Sci 94720-2020

UCB status (select all that apply):

	Faculty		Postdoc		Grad		Undergrad	X	Other	Staff

Other Personnel

Name of Other Personnel **Degree** **Title**
Valerie Morash

Email **Phone** **Fax**
valmo@berkeley.edu 642-7679

Department Name **Mailing Address**
OPTM-Vision Sci MC 2020

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)
10/27/08		

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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	
	N	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

X Not Funded

SPO - Funding

Funding - Other

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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

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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.

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;

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e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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.)

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) **2003-12-69**

Study Title

Visual-Haptic-Auditory Integration

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.

Sight, touch, and hearing all provide information about objects, such as shape, size, temporal properties, and position, but they obtain information differently. Sight derives from the retinal absorption of photons reflected from the surfaces of objects. Touch derives from the differential force on the fingers and hand created by the mechanical contact with objects. Hearing derives from the cochlea's reception of sound vibrations transmitted through the air. As a result of these differences, sight, touch, and hearing have advantages and limitations relative to each other.

The purpose of this research is to learn how human observers combine information from vision, touch, and sound. In particular, we seek to understand whether the nervous system capitalizes on the advantages of sensory systems when one of the senses is more efficient than another in the task at hand. We will conduct computational and experimental investigations in order to better understand the process of combination of visual, auditory, and haptic information in human perception. Our hypothesis is that sensory information is combined in a predictable fashion.

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).

Several studies have been done within our lab with similar procedures and equipment for vision and touch. These include:
Ernst, M.O., Banks, M.S., Bülthoff, H.H. (2000) Touch can change visual slant perception. Nature Neuroscience, 3, 1, 69-73.
Ernst, M.O. & Banks, M.S. (2002) Humans integrate visual and haptic information in a statistically optimal fashion. Nature, 415, 429-433.
Hillis, J.M., Ernst, M.O., Banks, M.S. & Landy, M.S. (2002) Combining Sensory Information: Mandatory

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Fusion Within, but Not Between Senses. Science, 298, 1627-1630.
Gepshtein, S. & Banks, M.S. (2003) Viewing geometry determines how vision and haptics combine in size perception. Current Biology, 13, 6, 483-488.
Trommershauser, J., Gepshtein, S., Maloney, L.T., Landy, M.S. and Banks, M.S. (2005) Optimal Compensation for Changes in Task-Relevant Movement Variability. The Journal of Neuroscience, 25, 7169-7178.
Gepshtein, S., Burge, J., Ernst, M.O. and Banks, M.S. (2005). The combination of vision and touch depends on spatial proximity. Journal of Vision, 5(11), 1013-1023.

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.

Non-UCB institutions

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.

Martin Banks, the lead investigator, has been a UC Berkeley professor since 1984 and the PI on multiple large research grants. He has over 75 publications and will be overseeing all projects done under this protocol. The other key personnel listed in this application is Valerie Morash. She is a UCB graduate student working with Professor Banks who has completed appropriate human subjects training and has experience working with human subjects. She will be conducting the actual procedures of the protocol.

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.

Subjects will be recruited from students in Optometry, Psychology, Bioengineering, Cognitive Science and Vision Science. Subjects will be 18-65 years of age. Subjects will not be vulnerable to coercion or to undue influence. Subjects may or may not be members of racial or ethnic minority groups; race, gender, and ethnicity will not be used as selection criteria, nor will records be kept of subjects' race, gender, or ethnicity.

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.

A maximum of 100 subjects will be needed since we will be doing variations of this study over the course of many years.

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.

Potential subjects will be recruited via e-mail sent to various UC Berkeley student e-mail lists. They will be informed in advance of all procedures and overall goals, but not about the specific experimental hypotheses. To prevent against potential coercion or undue influence, course instructors will never recruit from among their students; instead, a graduate student will do the recruiting. Additionally, recruitment materials will state that whether or not students participate will have no bearing on grades. Graduate students within the School of Optometry may volunteer to participate as research subjects in order that they may obtain research experience, but they will not be obligated to participate and choosing not to do so will have no bearing on their privileges or advancement in the program.

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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.**

See attached recruitment text. This text will be sent to various student email lists.

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).**

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.**

Subjects will be recruited from students in Optometry, Psychology, Bioengineering, Cognitive Science and Vision Science. Subjects will be 18-65 years of age. Subjects will not be vulnerable to coercion or to undue influence. Subjects may or may not be members of racial or ethnic minority groups; race, gender, and ethnicity will not be used as selection criteria, nor will records be kept of subjects' race, gender, or ethnicity.

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.**

n/a

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.

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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

Subjects who are not graduate students in the lab will be paid $12.00 per hour for their participation. Graduate students in the lab may volunteer to participate as human subjects, however, they are not required to participate and choosing not to do so will have no bearing on their privileges or advancement in the program. All graduate students are paid the same monthly stipend (which is at least $12.00 per hour) to do research irregardless of whether they participate as human subjects or not; therefore, graduate students who choose to participate as human subjects will not be paid separately on this hourly basis. Because graduate students in the lab are already being paid to do research whether they choose to be subjects or not, we believe that graduate students who volunteer to participate as subjects are receiving adequate compensation for their participation.

If subjects choose to discontinue their participation, they will still be paid for the time they put in. Subjects will not be required to provide social security numbers if they have student or staff id numbers. Identifiable personal data will be collected separately from consent documentation—identifiable personal data will be stored in locked file cabinets in an office of the PI.

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

The selected amount is similar to compensation for other psychophysical studies being carried out within the School of Optometry. We believe this compensation is sufficient to motivate subjects to return for repeated visits, while not so high as to create an undue influence to participate.

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.)**

There are no costs or charges 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.**

Subjects will be looking at a computer screen displaying the visual objects, and will either touch real (non-harmful) objects or put their thumb and index finger into thimbles that allow us to create the sensation of touching objects. They will wear headphones that play tones. Subjects will be asked to judge the size, location, temporal properties, or shape of objects using visual information alone, using touch information alone, using auditory information alone, or using multiple kinds of information. They will make responses by touching a real or virtual object in their field of view. Subjects will use either chin and forehead rests (adjusted to a comfortable position for each subject) or bite bars (custom-made mouthpieces) which are used to help minimize head movement).

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 experiments will take place in Professor Martin Banks' Vision Sciences Lab at the School of Optometry. All experiments will take place in the Banks lab at times agreed upon by both subject and researcher. Either Professor Banks or one of students listed as key personnel will conduct the sessions. Each session will last about 30-60 minutes, determined by the subject. The subject may end the session at any time. There will be a total of between 1 and 30 sessions per subject for a total time commitment of between 30 minutes and 30 hours, depending on the experiment.

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 taping will occur. Describe what will become of the tapes after the project (e.g.,**

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shown at scientific meetings, erased) and final disposition of the tapes.

n/a

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.

There are only minimal risks to the subjects. Staring at a CRT for extended periods of time can cause eyestrain and sitting in a rigid position for long periods of time can create back or neck strain. There is a small possibility that subjects might hear sounds at an uncomfortably loud volume if equipment is improperly set up. Some subjects will use individual bite bars (custom-made mouthpieces which are used to help minimize head movement) during the experiment. If the bite bars are not cleaned and stored properly, there is a slight risk (as with toothbrushes) of harmful bacterial growth or cross-contamination with other bite bars. While there is a small chance that the confidentiality of the information collected could be compromised, we will take care to prevent this from happening.

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

Subjects will be offered adjustable chairs and encouraged to find comfortable seated positions. Subjects will be encouraged to stop or take a break before they experience discomfort from staring at the CRT screen and sitting for prolonged periods. The subjects will be allowed to stop whenever they experience discomfort. They may choose to cease participation in the study at any time and for any reason. To reduce the small possibility that subjects might hear sounds at a higher-than normal volume if the equipment is improperly set up, experimenters will verify that settings are correct before beginning each session. Subjects' individual bite bars, which are marked with the subjects' initials or three-letter code used to identify that subject, will be handled and stored using the following hygienic protocol: after each use, the bite bars will be washed with soap and water, dried with paper towels, and stored separately from other bite bars. The research data (i.e. "de-identified" data) collected from subjects will not contain personal identifiers—the data will be designated only by subjects' initials, or if they prefer, a three-letter code. The research data will be kept on a firewall- and password-protected computer. "Identity-only" information such as subjects' signed consent forms and information needed by the Disbursements Office for subjects' payments will be saved in a locked file cabinet in an office of the Principal Investigator.

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.

Any unanticipated problem or serious adverse event (as defined in the CPHS Policies & Procedures) will be reported to the Director of the Office for Protection of Human Subjects as soon as possible (by fax, mail/delivery, phone, or email), but within no more than one week (7 calendar days) of the Principal

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Investigator learning of the incident. For protocols that are approved in eProtocol, an electronic "Incident Report" will need to be submitted via eProtocol, within no more than two weeks (14 calendar days) of 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).**

N/A. The study involves only 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.

There are no direct benefits to subjects. The results will benefit society by enhancing understanding of the mechanisms of multisensory perception in the coordination of visual, auditory, and haptic senses. These mechanisms are of particular importance to people who will be using virtual reality displays. This research will also help to develop teleoperation technologies for the remote control of fine mechanical manipulations, such as remote surgery and operation in danger zones (e.g., in the nuclear reactors and areas infested with hidden explosives).

13. Confidentiality

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

a) **Explain how subject privacy will be protected and how confidentiality of subject information will be maintained. Discuss who will have access to study records/specimens and how the records will be secured.**

The research data (i.e. “de-identified” data) collected from subjects will not contain personal identifiers—the data will be designated only by subjects’ initials, or if they prefer, a three-letter code. The research data will be kept either on a firewall- and password-protected computer. Information on the inter-pupillary distance of each subject will be linked to their initials or three-letter codes and also be kept on a firewall and password protected computer. (The inter-pupillary distance is necessary as it is used in calculating certain features of the stimuli. This distance is not a direct identifier of subjects.) If subjects agree, we will use their initials for publications of the research; if subjects prefer, we will use three-letter codes instead.
“Identity-only” information such as subjects’ signed consent forms (which will include their three-letter codes for subjects who prefer not to use their initials) and information needed by the Disbursements Office for subjects’ payments (names, addresses, phone numbers and either student id numbers, staff id numbers, or social security numbers) will be saved in a locked file cabinet in an office of the Principal Investigator.

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b) **Will subjects be asked to give permission for release of identifiable data (e.g., information, videotapes), now or in future? If so, explain here and include appropriate statements in consent materials.**

No identifiable data will be collected or released from the research data. Subjects will only be asked to give permission that their initials or three-letter codes be used.

c) **Will data be collected anonymously (i.e., no identifying information from subjects will be collected/ recorded that can be linked to the study data)? Data is not anonymous if there is a code linking it to personally identifiable information. Also, audio and video recordings are generally not considered to be anonymous unless distinguishing features can be successfully masked.**

Only subjects' initials or, if they prefer, a three-letter code will be recorded.

d) **If using existing data/biological specimens, will the researchers have access to a code linking the data to personally identifiable information?**

n/a

e) **If identifying information will be collected and linked to data/specimens, explain at what stage identifiers will be removed from the data/specimens. If identifiers will be retained, explain why this is necessary and how confidentiality will be protected.**

Identifiers are retained in order to be able to pay the subjects, but the "identity-only" data set is completely separate from the "de-identified" data set and is kept in a locked file cabinet in an office of the PI.

f) **If the data is coded, explain where the key to identifiers will be stored, how it will be protected, and who will have access to it.**

For subjects who prefer not to have their initials used, we will assign a three letter code, which will be written on their consent forms and saved in a locked file in an office of the PI.

g) **Indicate whether research data/specimens will be destroyed at the end of the study. If data will not be destroyed, explain why, where, in what format, how long it will be retained and who will have access to it.**

The research data (which does not contain personal identifiers) might be saved as text files on a password-protected computer for future analysis. This allows researchers an opportunity to go back and analyze the data further should new questions arise as a result of publication or presentation of the findings.

h) **Explain how data, audiotapes, videotapes, photographs, etc., will be stored and who will have access to them. Indicate at what point they will be transcribed and/or destroyed (if ever).**

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n/a

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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

Informed Consent

Consent/Waiver Description (e.g. Consent for Group A, Waiver for Group B, Surrogate Consent for Group C)	Consent form		
Consent Type	Consent Form		
Attach Consent Document (in PDF format)	X	Consent Document	2010-02-881_Banks_ConsentRenewed2013

Explain how, where, when, and by whom informed consent will be obtained. If any vulnerable subject groups are involved, discuss relevant considerations. Note: If attaching multiple consent forms and consent process has already been described for another consent form, simply refer to the other form (e.g., "consent process is the same as for Group A").

Potential subjects will be recruited via e-mail sent to various UC Berkeley student e-mail lists. They will be informed in advance of all procedures and overall goals, but not about the specific experimental hypotheses. To prevent against potential coercion or undue influence, course instructors will never recruit from among their students; instead, a graduate student will do the recruiting. Additionally, recruitment materials will state that whether or not students participate will have no bearing on grades. Graduate students within the School of Optometry may volunteer to participate as research subjects in order that they may obtain research experience, but they will not be obligated to participate and choosing not to do so will have no bearing on their privileges or advancement in the program.

When the potential subject comes to the laboratory, one of the key personnel listed on this application will describe the experimental procedure to the subject. The subject will be told that they can interrupt an experimental session or cease participating in the experiment at any time. If the subject agrees to participate, they will be asked to read and sign the consent form.

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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.

•<a href='http://cphs.berkeley.edu/informedconsent.html' target='_blank'> Child Assent and Parent Permission Guidelines, Templates, and Sample Forms

•Policies and Procedures on Child Assent and Parent Permission

Documents and Waivers

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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.

Document Type	Other
Document Name	FRM5-RenewalApp
Document Type	Recruitment Script(s)
Document Name	Visual_Haptic recruitment text
Document Type	Other
Document Name	2009-2010 Summary of Findings
Document Type	Other
Document Name	FRM6-AmendApp_rev
Document Type	CITI Certificate(s)
Document Name	Citi completion report_Morash

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* * * Assurance * * *

Assurance

As Principal Investigator, I have ultimate responsibility for the performance of this study, the protection of the rights and welfare of the human subjects, and strict adherence by all co-investigators and research personnel to CPHS requirements, federal regulations, and state statutes for human subject's 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 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.

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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.**
