Modification

Basic Info

Confirmation Number:	**iifjjjj**
Protocol Number:	**815432**
Created By:	**FRAZIER, LAUREN E**
Principal Investigator:	**BADLER, NORMAN I**
Protocol Title:	**Evaluation of Gesture-Based Controls for Robotic Systems**
Short Title:	**Gesture-Based Controls for Robotic Systems**
Protocol Description:	**In this thesis, I propose the use of smartphones for gesture-based control of robotic systems. The proposed controller will be evaluated by performing a set of carefully designed human factors experiments and computing a set of metrics (e.g. time taken to complete tasks) to measure the efficacy of the gesture-based control system.**
Submission Type:	**Social and Biological Sciences**

PennERA Protocol Status

Approved

Resubmission*
Yes

Are you submitting a Modification to this protocol?*

Yes

Current Status of Study

Study Status

Study has not begun (no subjects entered)

If study is currently in progress, please enter the following

Number of subjects enrolled at Penn since the study was initiated

0

Actual enrollment at participating centers

0

If study is closed to further enrollment, please enter the following

Number of subjects in therapy or intervention

0

Number of subjects in long-term follow-up only

0

IRB Determination
If the change represents more than minimal risk to subjects, it must be reviewed and approved by the IRB at a convened meeting. For a modification to be considered more than minimal risk, the proposed change would increase the risk of discomfort or decrease benefit. The IRB must review and approve the proposed change at a convened meeting before the change can be implemented unless the change is necessary to eliminate an immediate hazard to the research participants. In the case of a change implemented to eliminate an immediate hazard to participants, the IRB will review the change to determine that it is consistent with ensuring the participant′s continued welfare. Examples: Convened Board Increase in target enrollment for investigator initiated research or potential Phase I research Expanding inclusion or removing exclusion criteria where the new population may be at increased risk Revised risk information with active participants Minor risk revisions that may affect a subject′s willingness to continue to participate Expedited Review Increase in target enrollment at Penn where overall enrollment target is not exceeded or potentially sponsored research Expanding inclusion or removing exclusion where the new population has the same expected risk as the previous, based on similarities of condition Revised risk information with subjects in long-term follow-up Minor risk revisions with no subjects enrolled to date ** For track changes: turn on the reviewing toolbar (view ⇒ toolbars ⇒ reviewing). You can accept all changes from current point forward by clicking the arrow next to Accept Change icon in toolbar, and then clicking Accept All Changes in Document. Use either balloons with tracked changes OR-- to format for underlines (for additions) and strikethrough (for deletions) Either (1) click Show (in the reviewing toolbar) ⇒ options ⇒ "unclick use balloons in print and web layout" -- OR -- (2) use ctrl-U (for underline), and format ⇒ font ⇒ strikethrough (for strikethrough).
Expedited Review

Modification Summary
Please describe any required modification to the protocol. If you are using this form to submit an exception or report a deviation, enter 'N/A' in the box below.
Small changes to make wording more clear in several places.

Risk / Benefit
Does this amendment alter the Risk/Benefit profile of the study?
No

Change in Consent
Has there been a change in the consent documents?
Yes

If YES, please choose from the options below regarding re-consenting

Our site does not plan to obtain re-consent

Deviations

Are you reporting a deviation to this protocol?*

No

Exceptions

Are you reporting an exception to this protocol?*

No

Protocol Details

Resubmission*
Yes

Study Personnel

Principal Investigator

Name:	**BADLER, NORMAN I**
Dept / School / Div:	**1303 - Computer and Information Science**
Campus Address Mail Code	**6389**
Address:	**Room 304 Computer & Info Scie** **Levine 3330 Walnut St./6389**
City State Zip:	**Philadelphia PA 19104-6389**
Phone:	**215-898-5862**
Fax:	
Pager:	
Email:	**badler@seas.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**08/28/2012**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Study Contacts

Name:	**FRAZIER, LAUREN E**
Dept / School / Div:	**1300 - School of Engineering**
Campus Address Mail Code	
Address:	**RM 1109 SANSEAST** **3600 CHESTNUT STREET MB 1030**
City State Zip:	**PHILADELPHIA PA 19104-6106**
Phone:	**215-369-0266**
Fax:	
Pager:	
Email:	**lfrazier@seas.upenn.edu**
HS Training Completed:	**No**
Training Expiration Date:	
Name of course completed :	

Other Investigator

None

Responsible Org (Department/School/Division):

1303 - Computer and Information Science

Key Study Personnel

Name:	**KAPADIA, MUBBASIR T**
Department/School/Division:	**Computer and Information Science**
HS Training Completed:	**No**
Training Expiration Date:	
Name of course completed:	

Disclosure of Financial Interests*
Does any person who is responsible for the design, conduct, or reporting of this research protocol have a **FINANCIAL INTEREST**?
No

Certification
I have reviewed the *Financial Disclosure and Presumptively Prohibited Conflicts for Faculty Participating in Clinical Trials* and the *Financial Disclosure Policy for Research and Sponsored Projects* with all persons who are responsible for the design, conduct, or reporting of this research; and all required Disclosures have been attached to this application.
Yes

Social and Biological Sciences

Study Instruments
Discuss the particulars of the research instruments, questionnaires and other evaluation instruments in detail. Provide validation documentation and or procedures to be used to validate instruments. For well know and generally accepted test instruments the detail here can be brief. More detail may be required for a novel or new instrument. For ethnographic studies identify any study instruments to be used (i.e. for deception studies) and describe in detail where, when and how the study will be conducted and who or what are the subjects of study. Note: For more information on how to conduct ethical and valid ethnographic research, follow the link For oral histories or interviews provide the general framework for questioning and means of data collection. If interviews or groups settings are to be audio taped or video taped describe in detail the conditions under which it will take place. Include a copy of any novel or new test instruments with the IRB submission.
Hardware: A Roomba robotic vacuum cleaner, an Android phone, and a XBOX gamepad controller will be used in the study, as well as some tape/craft materials to create an obstacle course for the robot. Participants will use the gamepad and smartphone to navigate the Roomba robot in the obstacle course. Video Recording: The participants will be video taped while performing the experiment which will be used to compute quantitative metrics to evaluate the efficiency of the controllers. We will observe metrics like number of times the subject looks down at the controls, number of times the subject verbally acknowledges a mistake, etc. Having a video recording means that we could analyze those metrics offline, after the experiment. The video will not be made public and will not be associated with the subject's name. Evaluation: After performing the experiment, subjects will be administered a questionnaire to help us determine their subjective experience during the experiment. They will be questioned about their experience with video games and other control systems to ensure that the independent variable was the only contributing factor to the differences in their results. The questionnaire will use a 5-level Likert scale. Attached is a copy of the questionnaire. Finally, subjects will be asked if they would like to allow us to use the images we took of them during the study as more than data -- potentially in a paper we write, or on slides or on our website. They will be asked to sign a consent form if they agree, but will be told that none of their other participation will be affected by their choice, either way we will use their data, unless they choose to withdraw from the study. Although we will maintain a list of the subjects' names during and after the study, we will not associate the individual set of responses from any particular subject in any personally identifiable way.

Group Modifications
Describe necessary changes that will or have been made to the study instruments for different groups.
N/A: No groups

Method for Assigning Subjects to Groups
Describe how subjects will be randomized to groups.
N/A: No groups

Administration of Surveys and/or Process
Describe the approximate time and frequency for administering surveys and/or evaluations. For surveys, questionnaires and evaluations presented to groups and in settings such as high schools, focus group sessions or community treatment centers explain how the process will be administered and who will oversee the process. For instance, discuss the potential issues of having teachers and other school personnel administer instruments to minors who are students especially if the content is sensitive in nature. Describe the procedure for audio and videotaping individual interviews and/or focus groups and the storage of the tapes. For instance, if audio tape recording is to be used in a classroom setting, describe how this will be managed if individuals in the class are not participating in the study. Explain if the research involves the review of records (including public databases or registries) with identifiable private information. If so, describe the type of information gathered from the records and if identifiers will be collected and retained with the data after it is retrieved. Describe the kinds of identifiers to be obtained, (i.e. names, social security numbers) and how long the identifiers will be retained and justification for use.
Before subjects begin, they will sign a consent form and be briefed on the way to use each controller. Approx. 15 min. Each subject will navigate a robot through an obstacle course several times (once for each control scheme). The experiment itself should take approx. 20 minutes. After the experiment, the subject will complete one questionnaire (~15 minutes) after he/she finishes with the robot. All video footage will be stored on a hard drive. No other records will be reviewed. Total time: 50 minutes.

Data Management
Describe how and who manages confidential data, including how and where it will be stored and analyzed. For instance, describe if paper or electronic report forms will be used, how corrections to the report form will be made, how data will be entered into any database, and the person(s) responsible for creating and maintaining the research database. Describe the use of pseudonyms, code numbers and how listing of such identifiers will be kept separate from the research data.
The video data will be stored digitally, on a hard drive. The questionnaires will be taken online (using SurveyMonkey) and stored digitally as well. Subjects will be assigned a number that will be used when transcribing the questionnaire rather than identifying information. The data will only be managed by the PI and primary study contact. Although we will maintain a list of the subjects' names during and after the study, we will not associate the individual set of responses from any particular subject in any personally identifiable way.

Human Source Material*
Does this research include collection or use of human source material (i.e., human blood, blood products, tissues or body fluids)?
No

Medical Information Disclosure*
Does the research proposal involve the use and disclosure of research subject's medical information for research purposes?
No

If the answer is YES, indicate which items is is provided with this submission:

Use of UPHS services*
Does your study require the use of University of Pennsylvania Health System (UPHS) services, tests or procedures* whether considered routine care or strictly for research purposes?
No

Primary Focus*
Other

Protocol Interventions

	Sociobehavioral (i.e. cognitive or behavioral therapy)
	Drug
	Device - therapeutic
	Device - diagnostic (assessing a device for sensitivity or specificity in disease diagnosis)
	Surgical
	Diagnostic test/procedure (research-related diagnostic test or procedure)
	Obtaining human tissue for basic research or biospecimen bank
	Survey instrument
x	**None of the above**

The following documents are currently attached to this item:

There are no documents attached for this item.

Sponsors

Business Administrator

Name:	**WEST, MARK**
Dept / School / Div:	**1322 - Moore Business Offices**
Phone:	**215-898-2442**
Fax:	
Pager:	
Email:	**MWEST@SEAS.UPENN.EDU**

Funding Sponsors

Name:	**DEPARTMENT OF THE ARMY**
Type:	**UPENN Federal**

Project Funding*
Is this project funded by or associated with a grant or contract?
Yes

Sponsor Funding
Is this study funded by an industry sponsor?
No

Status of contract

The following documents are currently attached to this item:

Grant Application (h4.1.doc)

Protocol

Objectives

Overall objectives
Robotic control systems are becoming more common, especially in the military. With military applications, there are lives at stake, so having the most efficient, intuitive control system can make a large difference in the success of a mission and the safety of the soldiers involved. Arm and hand gestures are typical human forms of communication, so applying that to a robotic control system can yield a more intuitive system. Varcholik et. al. describe a gesture based control system that uses the Nintendo Wiimote to determine arm/hand gestures to control a robot. In this thesis, I propose the use of smartphones for gesture-based control of robotic systems. The proposed controller will be evaluated by performing a set of carefully designed human factors experiments and computing a set of metrics (e.g. time taken to complete tasks) to measure the efficacy of the gesture-based control system.

Background
"Interactions and Training with Unmanned Systems and the Nintendo Wiimote" (Varcholik, Barber, and Nicholson) describes a gesture based control system that uses the Nintendo Wiimote to determine arm/hand gestures and control a robot. They then conducted a study where subjects used Wiimote gesture system and a more standard system and filled out a survey to indicate how effective the Wiimote system was as compared to the standard system. This project attempts to do something similar with smartphones by utilizing a framework first proposed by Robert Neßelrath in "TaKG, A Toolkit for Automatic Classification of Gestures".

Study Design

Design
Participants will use a gamepad and a smartphone to guide the robot through an obstacle course. They will first try the gamepad, which will be an XBOX 360 controller. On the smartphone, they will try a button based control scheme, a tilt based control scheme, and a large gesture based control system. The order in which they attempt these will be randomly selected. Some metrics that will be recorded are the speed with which each trial is completed, and the number of times the robot goes outside the boundaries of the obstacle course. At the end, participants will fill out a questionnaire regarding their performance on the obstacle course.

Study duration
This study is on-going research that will last about one month. Subjects participating in the study will be limited to 1 hour per session, for one session each.

Characteristics of the Study Population

Target population
Adult (college aged) subjects who are physically able enough to move their arms.

Subjects at Penn
30

Subjects at Sites Other than Penn
0

Vulnerable Populations

	Children (refer to SOP 501 for definition of children) Form
	Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form
	Fetuses and/or Neonates Form
	Prisoners Form
	Other
x	**None of the above populations are included in the research study**

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject recruitment
Posters will be put in campus buildings advertising the study. No referrals necessary.

The following documents are currently attached to this item:

Subject recruitment (flyer_irb.pdf)

Subject compensation*
Will subjects be financially compensated for their participation?
No

The following documents are currently attached to this item:

There are no documents attached for this item.

If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document

N/A

Study Procedures

Procedures
The subject will be briefed on the purpose of the study and introduced to the robot and control equipment. The subject will then perform several trials (in a randomly selected order) using the different control schemes. Their performance will be timed/recorded. After the trials, the subject will fill out a questionnaire about their background and experience during the trials.

The following documents are currently attached to this item:

There are no documents attached for this item.

Analysis Plan
For each trial, we will record the total time taken to finish the trial, the number of fouls (straying outside of the course boundaries). We will also look at the data from the questionnaire, like subjects' rankings of the control schemes, and the video data (e.g., number of times the subject had to look down at the controls, trajectories of hand gestures, times the subject asked for help, times the subject acknowledged making a mistake). The average performance for each control scheme will be determined using arithmetic methods or ANOVA to compare the different control schemes. The analysis of variance would be computed for the average time taken to finish a trial, average number of fouls, average difficulty reported by subjects, etc.

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject Confidentiality
Personal information will be collected on the consent form, and in the form of the videos, but will not be linked to the data. We will be using identifiers for the subjects on the consent , rather than personal information. The consent forms, survey data, and video data will be stored on an encrypted hard drive. After the study is complete, the relevant stills and survey data will be included in a paper (possibly for publication) to be shared with the RCTA. All the original data will then be destroyed by wiping the hard drive.

Data Disclosure
Will the data be disclosed to anyone who is not listed under Personnel?
Mubbasir Kapadia, CIS Postdoc

*Data Protection**

	Name
	Street address, city, county, precinct, zip code, and equivalent geocodes
	All elements of dates (except year) for dates directly related to an individual and all ages over 89
	Telephone and fax number
	Electronic mail addresses
	Social security numbers
	Medical record numbers
	Health plan ID numbers
	Account numbers
	Certificate/license numbers
	Vehicle identifiers and serial numbers, including license plate numbers
	Device identifiers/serial numbers
	Web addresses (URLs)
	Internet IP addresses
	Biometric identifiers, incl. finger and voice prints
	Full face photographic images and any comparable images
	Any other unique identifying number, characteristic, or code
x	**None**

Consent

1. Consent Process

Overview
Consent will be obtained through the signing of a form after a subject volunteers for the study. There will be a brief (several minute) waiting period between informing the prospective participant and obtaining the consent. The language understood by the prospective participant is similar to the following: He/she has read and understand this consent form. He/she gives permission for the project personnel to use the images/videos collected as a result of this study for data collection purposes. Anonymity in all publications will be maintained unless he/she gives written consent to use his/her image. He/she does not waive any of his/her legal rights by signing this form. His/her signing of this form does not release the investigator, the sponsor, the institution nor its agents from liability for negligence.

Risk / Benefit

Potential Study Risks
The potential risks in this project are minimal. Possible risks are muscle strains and sprains while gesturing. If this occurs, the study will stop, and the subject can stop or continue at a future time. The electronic devices involved are not expected to cause any physical harm.

Potential Study Benefits
There are no direct benefits to the subject for choosing to participate in this study. However, participation could contribute to the understanding of gesture-based control systems, which could benefit the subject indirectly and may help other people in the future.

Risk / Benefit Assessment
The potential benefits outweigh the potential risks of the study. The risks are minimal, and the benefit could lead to technology that could be widely used, or used to save lives in the future.

General Attachments

The following documents are currently attached to this item:

Informed consent form (consent_form.doc)

Additional forms (imageconsentform.doc)

Questionnaires (questionnaire.doc)

Additional forms (citi_completion_report_mubbasir.pdf)

Additional forms (reply_doc.pdf)

Additional forms (citicompletionreportlfrazier.pdf)