

Johns Hopkins University  
Homewood Institutional Review Board (HIRB)

**Application for Expedited/Full Board Review**

All human participant research under the jurisdiction of the Homewood Institutional Review Board (HIRB) must be reviewed and approved by HIRB and conducted in full accordance with all applicable sections of the Johns Hopkins University HIRB Policies and Procedures. The Policies and Procedures can be located at:

<http://web.jhu.edu/Homewood-IRB/images/forms/PP%20042511.pdf>

Some nonexempt studies involving human research participants may qualify for expedited instead of full board review. The application form is the same for expedited and full board review, but studies qualifying for expedited status usually are reviewed by only one or two HIRB members rather than by the full board. *Expedited* review is a term drawn from Federal regulations to refer only to the type of review process (these regulations and the expedited review categories may be found in 45 CFR [Code of Federal Regulations] 46). Expedited review is not necessarily faster than full board review. HIRB is ultimately responsible for determining whether studies meet the criteria required for expedited review.


It is preferred that ***Applications for Expedited/Full Board Review*** and study documents are emailed to [hirb@jhu.edu](mailto:hirb@jhu.edu) and should be submitted by the Principal Investigator. If you have any questions, please contact us.

Homewood Institutional Review Board (HIRB)  
Johns Hopkins University  
AMR II, Room 7  
(Basement, by Fresh Foods)  
Baltimore, MD 21218  
Phone: (410) 516-6580  
Fax: 410-516-0150  
E-mail: [hirb@jhu.edu](mailto:hirb@jhu.edu)

Johns Hopkins University  
Homewood Institutional Review Board (HIRB)

**Application for Expedited/Full Board Review**

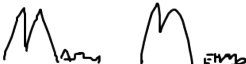
**PRINCIPAL INVESTIGATOR**

Name:	Dr. Russell H. Taylor	Degree /Title: Director, Center for Computer-Integrated Surgical Systems and Technology
Position:	JHU Faculty If Other, Please Specify:	
Department:	Computer Science	Mailing Address: Dept of Computer Science The Johns Hopkins University Baltimore, MD 21218
Phone:	410-516-6299	
Fax:	410-516-4410	
E-mail:	rht@jhu.edu	
Signature: -		Date: 15 March 2012

**STUDENT INVESTIGATOR/CO-INVESTIGATORS (IF APPLICABLE)**

*Please complete this section only if this research project is being conducted primarily by a student. Some examples may include a student thesis, Woodrow Wilson Fellowship project, or Public Health Studies project. Student Investigators must have a faculty member serve as Principal Investigator for all research projects with human participants and therefore, the Supervisor Form should also be filled out and submitted with this application.*

*For any additional investigators on this study (e.g., students, consultants) please complete a Research Team Members Form.*

Name:	Manish Mehta	Degree /Title: BME BS (expected W2012)
Position:	Other If Other, Please Specify:	JHU Undergraduate Student
Department:	Biomedical Engineering	Mailing Address: 3900 N Charles St Apt. 1201 Baltimore, MD 21218
Phone:	330/307-0673	
Fax:	N/A	
E-mail:	mmehta5@jhu.edu	
Signature: Manish Mehta		Date: 3 March 2012

## ADDITIONAL RESEARCH TEAM MEMBERS

Research team members include anyone — whether affiliated with the Johns Hopkins University or not — who (a) interacts with research participants (e.g., in recruiting, obtaining informed consent, collecting data, or debriefing); (b) prepares materials for use with participants (e.g., letters to potential participants, interview protocols); or (c) has access to data collected from participants.

*Additional research team members on this study?*  No  Yes *!!attach Research Team Member Form for each*

## RESEARCH PROTOCOL

### STUDY TITLE

Comparing the Efficacy and Intuitiveness of Various Master-Slave Interfaces for the Dexterous Manipulator (DM)

### STUDY SITE(S)

Where will the study be conducted? Check all locations that apply.

- |  |  |
|--|--|
| <input type="checkbox"/> Applied Physics Laboratory (APL)    | <input type="checkbox"/> Peabody Institute                               |
| <input type="checkbox"/> Carey Business School               | <input type="checkbox"/> School of Advanced International Studies (SAIS) |
| <input type="checkbox"/> Krieger School of Arts and Sciences | <input type="checkbox"/> School of Education                             |
| <input type="checkbox"/> Kennedy-Krieger Institute (KKI)     | <input checked="" type="checkbox"/> Whiting School of Engineering        |

Other U.S. Site(s). Specify:

International\*\* Site(s). Specify: *\*\*contact the HIRB for additional requirements.*

### FUNDING STATUS

Indicate the project's funding status below. *Submit the complete grant proposal and application.*

- Project is currently funded  
Funding Agency (e.g., NSF):  
Grant/Contract Number:
- Project has been submitted for funding.  
Funding Agency (e.g., NSF):
- No Funding Obtained or Applied For.

## PURPOSE OF THE STUDY

Describe the goals of the study clearly below.

The goal of this study is to compare the efficacy and intuitiveness of several mapping schemes between the motion of a controller (PHANTOM® Premium) and the corresponding motion of a custom-built robot (DM) meant for eventual use in Revision Total Hip Arthroplasties (i.e. if the controller is moved in some way, the DM will respond in some corresponding and predictable fashion).

## DESIGN & METHODOLOGY

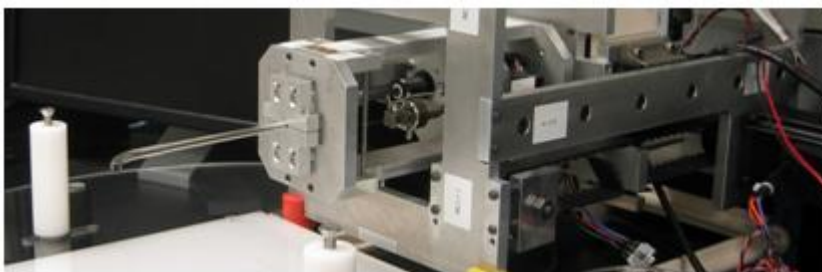
Describe the design and methodology of the study clearly below.

The trials will involve 20 subjects who have no experience with any kind of surgery. Subjects will be alternately assigned so as to create even-sized groups (or as close to even as possible). The idea is to gauge how easily each subject can learn to use the interface effectively, allowing us to measure how intuitive each interface is. An apparatus will be built that has three posts of different heights. On each post will be a colored marker in a different orientation.

Subjects will be asked to move the PHANTOM® (see Fig. 1) so as to cause the robot (see Fig. 2) to touch the colored markers in a given order. The time it takes the subject to perform this task will be recorded. Subjects will then be asked to repeat the task until the recorded time drops below some threshold (TBD). Each group will utilize a different mapping (out of 2-3 total mappings) from the PHANTOM® to the robot. Times and number of trials to threshold will be compared between groups.



**Figure 1:** PHANTOM® Premium Haptic Controller



**Figure 2:** Dexterous Manipulator

## PROCEDURES & ACTIVITIES

Describe the study's procedures and activities that participants will be asked to perform. *Attach all surveys, interview questions and guidelines, and other relevant materials you will use in this study.*

Subjects will be alternately assigned so as to create even-sized groups (or as close to even as possible). Subjects will be asked to move the PHANTOM® so as to cause the robot to touch the colored markers in a given order. The time it takes the subject to perform this task will be recorded. Subjects will then be asked to repeat the task until the recorded time drops below some threshold (TBD). Each group will utilize a different mapping (out of 2-3 total mappings) from the PHANTOM® to the robot. Times and number of trials to threshold will be compared between groups.

## DATA ACCESS

If the study involves materials (e.g., data, documents, records, specimens) that have been or will be collected for **non-research** purposes, describe how authorization for access to these materials will be obtained.

All materials from this trial will have been collected for research purposes.

## PARTICIPANTS

Describe the participant population(s) and the total number of participants to be enrolled. *If children will participate, complete and attach the Child Checklist and the Assent Checklist.*

\*\*Please note that if during your research, you decide to increase the number of participants beyond the number provided here, you must submit an amendment to notify the IRB beforehand.

This trial will involve approximately 20 subjects, selected from the student population at the JHU Homewood campus. They may be undergraduate students or graduate students.

## SPECIAL CATEGORIES OF PARTICIPANTS

Check all categories that apply to this study. Additional regulations and review requirements apply to some categories. Additional instructions for these categories can be found in the Instructor's Manual and HIRB Standard Operating Policies & Procedures.

JHU Students

JHU Employees

<input type="checkbox"/> Children (< 18 years old) ..... if checked, give age range: _____ <p><b>Children</b> are persons who have not attained the legal age at which they may consent to treatments or procedures involved in research under the applicable law of the jurisdiction in which the research will be conducted. In the State of Maryland, the legal age for consent is eighteen years or older. Any person under the age of 18 in Maryland is considered a minor and cannot legally grant consent. Please note that undergraduates under the age of 18 in Maryland are considered minors.</p> <p><i>If your study will involve children, you must obtain parental consent – please attach the Parental Permission form. Also please complete and attach the Child Checklist, and the Assent Checklist with the assent form or assent script to be used with your participants. An Assent Template is available on the HIRB website.</i></p>
<input type="checkbox"/> Cognitively-Impaired Individuals
<input type="checkbox"/> Individuals with Limited or No Reading Skills
<input type="checkbox"/> Non-English Speakers
<input type="checkbox"/> Pregnant Women/Fetuses
<input type="checkbox"/> Prisoners

**INCLUSION CRITERIA**

Describe the criteria participants must meet to be included in the study.
To be included in the study, subjects must have full use and control of their arms and hands as well as their vision. They must also have no experience performing surgery. They must be 18 or older. They must be fluent in English and capable of following directions.

**EXCLUSION CRITERIA**

Describe the criteria for excluding individuals from the study.
In addition not meeting the above 'inclusion criteria,' subjects will be excluded if their inclusion carries the risk of danger to researchers, other test subjects, or the robot. Subjects will also be excluded if their inclusion could engender a conflict of interest.

**PARTICIPANT RECRUITMENT**

In the area below, describe how you will identify and recruit participants. <i>Attach copies of any recruitment materials (e.g., ads, bulletin board notices, e-mails, phone scripts).</i>
Participants will be recruited via advertisements on Homewood campus and ‘Today’s Announcements’ sent out to students at the Homewood campus as we are looking to utilize students as subjects.

## COMPENSATION

Describe how participants will be compensated for their participation.

Participants will not be compensated for their participation.

## RISKS

Please consider the risks your study may pose to participants, including physical, psychological, social, economic, and other risks or harms. In the area below, explain any risks posed by your study **or** state that your study poses no risks to participants.

The risks associated with participation in this study are no greater than those encountered in daily life.

## MINIMIZATION OF RISKS

Explain the procedures for minimizing any risks to participants, including procedures for protecting the anonymity of participants and confidentiality of data.

Risks to the patient are minimal as the robot is small (~6mm diameter) and has a limited workspace than can easily be avoided. It also has hardware stops, including a kill switch. Further, the subjects will be kept physically apart from the robot, so that no contact between the robot and the subject is possible. The only contact between subjects and apparatus will be the contact between the subjects hand and the PHANTOM® handle. The PHANTOM® is a commercial device specifically designed for haptic applications. Anonymity of subjects will be maintained by assigning each a code number under which their times and responses will be filed. No written or electronic record of correspondences between code numbers and names will be kept.

## BENEFITS

Describe any potential benefits to participants and/or society. Be realistic in your assessment of potential benefits.

This test is the first step in improving the way Revision Total Hip Arthroplasty is done. As hip implants begin to wear, they compromise the integrity of surrounding bone and force the need for revision surgery. Current manual revision surgery is difficult, tedious, and not very effective. The robot aims to rectify this by increasing the surgeon's coverage of the damage and making the surgery more effective. Our trials will assist in the development of an intuitive way to control the robot to make its use as natural for the surgeon as possible.

## DOCUMENT STORAGE

Describe how and where the data will be stored while the research is ongoing and how/where the data will be stored at the completion of the study.

\*\*Please note that Federal regulations require all research forms and data, including signed informed consent documents, to be kept for a minimum of three years (or if the study enrolls children, until all children enrolled are at least 18 years of age) after the completion of the study. If the PI or student researcher leaves JHU within this three year period, the original research documents must remain at JHU with the Academic Department (or with the PI in cases of student research projects). Copies can be taken off-site, but all original research records are property of JHU and must remain on campus.

Data (including signed consent forms) will be secured in a locked drawer in Elisa Ahmanson's office (JHU Homewood, Hackerman 118). Copies of anonymized data (identified only by subject number) will be kept by the investigators and used for data analysis.

## INFORMED CONSENT

Except in certain circumstances, Federal regulations [45 CFR 46.116-117] require that written informed consent be obtained for all participants. Consent must be obtained either from the participants themselves or, for participants unable to give consent, from their legally authorized representatives (such as a parent or guardian in the case of children).

### Instructions

1. Please review the informed consent sections below and complete all that apply to your study. Do not complete sections that do not apply to your study, or state "n/a".
2. Include with your application all informed consent documents (e.g., written consent forms or scripts for oral consent procedures) to be used in the study. Please carefully review all informed consent documents prior to submission to check for any errors (e.g., typos, incomplete information). Incomplete or poorly prepared consent forms will delay the review process.
3. To prepare the written consent form for your study, please refer to the appropriate consent form template(s) (Written Informed Consent, Parental Permission, Assent of Minor) found on the HIRB website. Please **edit** the template(s) to produce your consent form(s). These templates may be used as guides when preparing oral consent scripts.

## INFORMED CONSENT: WAIVERS & ALTERATIONS

Under certain circumstances, Federal regulations allow for waiver of informed consent documentation, in which case oral consent will be obtained, and alterations or waiver of some or all consent requirements. Please indicate below if departures from standard written informed consent procedures are requested.

- Request Use of Oral Consent (i.e., Waive Documentation Requirement). *Complete and attach the Use of Oral Consent Form along with the script for oral consent.*
- Waiver or Alteration of Informed Consent Requirements. *Complete and attach the Informed Consent Requirements Waiver/Alteration Form.*
- Waiver of Parental Permission. *Complete and attach the Informed Consent Requirements Waiver/Alteration Form.*
- Waiver of Child Assent. *Complete and attach the Assent Checklist.*



### **INFORMED CONSENT: CHILDREN**

If any study participants will be children, parental permission (consent) must be obtained, unless HIRB waives this requirement. Child assent must be obtained from children who can provide it, unless HIRB waives this requirement. *Unless applying for waivers, complete and attach the Parental Permission form and the Assent Checklist, with the assent form or assent script to be used, if applicable. A Parental Permission Template and an Assent Template are available.*

### **INFORMED CONSENT: COGNITIVELY-IMPAIRED INDIVIDUALS**

If any potential participants are likely to be cognitively impaired or have any disabilities that may affect their ability to understand a consent form or give consent, please complete the sections below.

Please describe how the participants' capacity for consent will be determined.

N/A

Please describe how consent will be obtained for participants unable to give consent.

N/A

### **INFORMED CONSENT: INDIVIDUALS WITH LIMITED READING ABILITY**

Describe how consent will be obtained from individuals with no or limited reading ability.

N/A

### **INFORMED CONSENT: NON-ENGLISH SPEAKERS**

Describe how consent from non-English speakers (and those with limited English) will be obtained. Attach all informed consent documents in English and in translation – translations must be certified for accuracy by a native speaker.

N/A

### **CONFLICTS OF INTEREST**

Please indicate whether the principal investigator or any other key research personnel for this study have any potential conflicts of interest. Potential conflicts of interest arise when, for example, investigators have an interest in or serve as an officer for an outside entity whose financial interests may be affected by the research. (\* see [JHU Conflict of Interest Policies and Procedures](#))



No



Yes. Please describe the nature of the potential conflict.

## INVESTIGATOR TRAINING

University policy requires that **ALL** individuals engaged in human participant research complete training in human research protections. Certification should be renewed every five years. If proof of training has been submitted to the HIRB for other research, it will remain on file until due for renewal. *If proof of training is not already on file with HIRB, please submit a copy for every team member with this application.* HIRB's training policy can be found on the HIRB website and training can be completed at [www.citiprogram.org](http://www.citiprogram.org).

Training completed within last five years       Attached       on file with HIRB

## APPLICATION CHECKLIST

To ensure that your application is complete, please complete the checklist below for all items that apply to your study. All signatures must be obtained, and applicable additional forms and documentation must be fully completed before the review process can begin.

<input checked="" type="checkbox"/> Signature of Principal Investigator	<input checked="" type="checkbox"/> Informed Consent Forms/Oral Script
<input checked="" type="checkbox"/> Signature of Student Investigator/Co-Investigator	<input type="checkbox"/> Request Use of Oral Consent
<input checked="" type="checkbox"/> Research Team Members Forms	<input type="checkbox"/> Waiver/Alteration of Informed Consent Requirements
<input checked="" type="checkbox"/> Certificates of Training in Human Participant Research	<input type="checkbox"/> Child Checklist
<input type="checkbox"/> Grant Proposal and Application	<input type="checkbox"/> Parental Permission Form
<input checked="" type="checkbox"/> Surveys, Questionnaires, Interview Guides, and Other Relevant Measures Used in the Study	<input type="checkbox"/> Assent Checklist
<input checked="" type="checkbox"/> Recruitment Materials (e.g., Flyers, Ads, Invitations)	<input type="checkbox"/> Assent Form/Script
	<input checked="" type="checkbox"/> Supervisor Form (if student research)
	<input type="checkbox"/> Site permission (if not conducted at JHU campus or facility)
	<input type="checkbox"/> Contact information for expert (if international research)