

**Homewood Institutional Review Board**

3400 N. Charles Street - AMR2, Rm007  
Baltimore MD 21218-2685  
410-516-6580 \_ <http://web.jhu.edu/Homewood-IRB/>

Michael McCloskey  
Chair

April 3, 2012

Russell Taylor, PhD  
Manish Mehta, student researcher  
WSE Computer Science  
N.E.B. 224

Re: HIRB No. 2012041 / Comparing Efficacy and Intuitiveness of Various Master-Slave Interfaces  
for the Dexterous Manipulator (DM)

The research identified above has been approved by the Homewood IRB after an expedited review of the protocol. The research qualifies for expedited review under Federal regulation 45CFR46.110(b)(1), research category No. 7. Approval will be reported to the full Board for its concurrence at the next meeting.

Approval is valid for *six months* and will expire on **October 2, 2012**. The research may not continue past this date without re-approval by the IRB. An application for continuing review must be submitted to the Homewood IRB at least **six weeks prior** to the expiration of this approval. No changes may be made to the protocol or the consent form without the approval of the Board. Please keep in mind, **it is your responsibility to inform the Board of any adverse consequences to subjects** that occur in the course of the study.

Please keep a copy of this letter for future reference. Protocol documents which contain an IRB-stamp that you received electronically with this approval letter must be utilized when recruiting participants or obtaining informed consent. The approved materials containing the original stamp are available from the HIRB office upon request

Thank you for contacting the Homewood IRB about this research and for providing the requested information to make this determination. Your cooperation is greatly appreciated. If you have any questions, please do not hesitate to contact the HIRB at (410) 516-6580 or [HIRB@jhu.edu](mailto:HIRB@jhu.edu).

**Homewood IRB**

cc: Research Administration

Funded by: None /

Johns Hopkins University  
Homewood Institutional Review Board (HIRB)

**Informed Consent Form**

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

**Principal Investigator:** **Dr. Russell H. Taylor, Director, Center for Computer-Integrated Surgical Systems and Technology**

**Date:** 15 March 2012

**PURPOSE OF RESEARCH STUDY:**

The purpose of this research study is to determine which of a number of mappings between the motion of a controller and the corresponding motion of a robot is the most intuitive and efficient. The robot is intended to be used in hip surgery so the more intuitive and efficient the mapping, the better.

We anticipate that approximately 20 people will participate in this study.

**PROCEDURES:**

You will be asked to move a PHANTOM® Premium (see Fig. 1), which controls a robot (see Fig. 2). You will test what moving the PHANTOM® causes the robot to do under supervision of a researcher who will assist you. The researcher will explain how to use the PHANTOM® and answer any question you may have about it or the robot.

Once you are ready, you will be asked to move the PHANTOM®, thereby moving the robot. Your goal is to touch three colored markers in sequence. The markers will be on posts at different heights and with different orientations. Your time will be recorded

You will then be asked to repeat this task until your time falls below a pre-determined threshold.

Your participation in the study will last for one session that will last approximately 30 minutes.



Figure 1

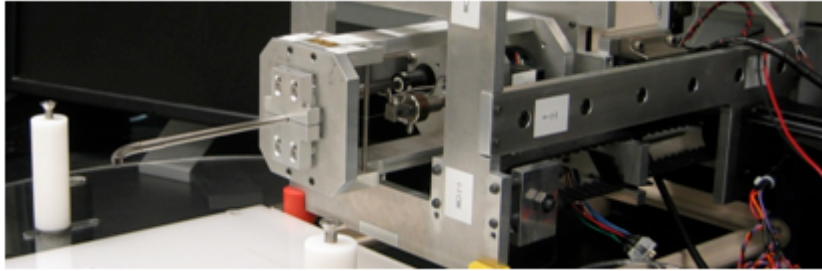


Figure 2

### **RISKS/DISCOMFORTS:**

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

### **BENEFITS:**

There are no direct benefits to you from participating in this study.

This study may benefit society if the results lead to a better understanding of interfacing the PHANTOM® with the robot. The robot is intended to be used in hip revision surgery, and the more intuitive the interface, the more smoothly the surgery will go.

### **VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW:**

Your participation in this study is entirely voluntary: You choose whether to participate. If you decide not to participate, there are no penalties, and you will not lose any benefits to which you would otherwise be entitled.

If you choose to participate in the study, you can stop your participation at any time, without any penalty or loss of benefits. If you want to withdraw from the study, please contact the researchers at [mmehta5@jhu.edu](mailto:mmehta5@jhu.edu) and let them know.

### **CONFIDENTIALITY:**

Any study records that identify you will be kept confidential to the extent possible by law. The records from your participation may be reviewed by people responsible for making sure that research is done properly, including members of the Johns Hopkins University Homewood Institutional Review Board and officials from government agencies such as the National Institutes of Health and the Office for Human Research Protections. (All of these people are required to keep your identity confidential.) Otherwise, records that identify you will be available only to people working on the study, unless you give permission for other people to see the records.

Code numbers will be used on data sheets in place of names, and no written or electronic record of correspondence between code numbers and names will be kept. All records will be kept in a locked drawer.

### **COMPENSATION:**

You will not receive any payment or other compensation for participating in this study.

### **IF YOU HAVE QUESTIONS OR CONCERNS:**

You can ask questions about this research study now or at any time during the study, by talking to the researcher(s) working with you or by calling Manish Mehta, at 330/307-0673, or contact the

Principal Investigator Dr. Russell Taylor at 410-516-6299. You may also email the researchers at mmehta5@jhu.edu.

If you have questions about your rights as a research participant or feel that you have not been treated fairly, please call the Homewood Institutional Review Board at Johns Hopkins University at (410) 516-6580.

## **SIGNATURES**

### **WHAT YOUR SIGNATURE MEANS:**

Your signature below means that you understand the information in this consent form. Your signature also means that you agree to participate in the study.

By signing this consent form, you have not waived any legal rights you otherwise would have as a participant in a research study.



Do not sign after the expiration date of: 10/02/2012

### **FOR PARTICIPANTS CAPABLE OF GIVING CONSENT:**

Participant's Signature

Date

Signature of Person Obtaining Consent  
(Investigator or HIRB Approved Designee)

Date

# PARTICIPANTS NEEDED FOR A RESEARCH STUDY TO TEST A ROBOT-CONTROLLER



## We Need You

Do you have 30 minutes to spare? Would you like to help in the development of a new surgical robot?

Email us about participating in this research study at [mmehta5@jhu.edu](mailto:mmehta5@jhu.edu) (Subject line—'Robot-controller interface trial') for more information!

(must be 18 or older)

This research project is conducted under IRB approval #2012041, PI: Russell Taylor

Robot-Controller trials  
Email: [mmehta5@jhu.edu](mailto:mmehta5@jhu.edu)

Robot-Controller trials  
Email: [mmehta5@jhu.edu](mailto:mmehta5@jhu.edu)

Robot-Controller trials  
Email: [mmehta5@jhu.edu](mailto:mmehta5@jhu.edu)

Robot-Controller trials  
Email: [mmehta5@jhu.edu](mailto:mmehta5@jhu.edu)

Robot-Controller trials  
Email: [mmehta5@jhu.edu](mailto:mmehta5@jhu.edu)

Robot-Controller trials  
Email: [mmehta5@jhu.edu](mailto:mmehta5@jhu.edu)

Robot-Controller trials  
Email: [mmehta5@jhu.edu](mailto:mmehta5@jhu.edu)

Robot-Controller trials  
Email: [mmehta5@jhu.edu](mailto:mmehta5@jhu.edu)

Robot-Controller trials  
Email: [mmehta5@jhu.edu](mailto:mmehta5@jhu.edu)

Robot-Controller trials  
Email: [mmehta5@jhu.edu](mailto:mmehta5@jhu.edu)

Robot-Controller trials  
Email: [mmehta5@jhu.edu](mailto:mmehta5@jhu.edu)

The following will be submitted to run as a 'Today's Announcement' for both undergraduate and graduate students:

Do you have 30 minutes to spare? Would you like to help in the development of a new surgical robot? We need participants for a research study. Participants will put the robot through its paces and report to researchers what they think. For more information, please contact Manish at [mmehta5@jhu.edu](mailto:mmehta5@jhu.edu). Timing is flexible. Must be 18 or older.

