

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

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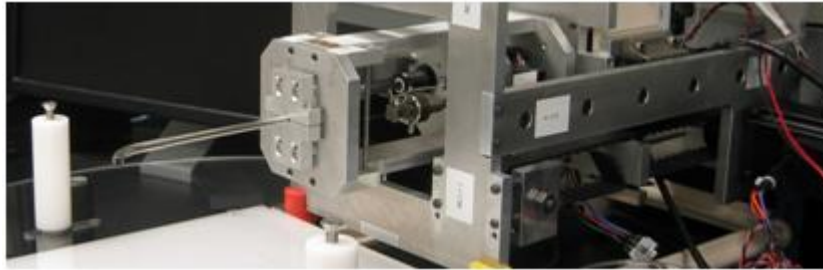


Figure 2

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 mmehra5@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.

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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, one of the researchers, at 330/307-0673. 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: _____

FOR PARTICIPANTS CAPABLE OF GIVING CONSENT:

Participant's Signature

Date

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

Date