**Revisions to Consent Form**

**IRB Application 2008J1769**

Please note the following changes have been made to the consent form for the study An Evaluation of a Real-time Body Visualization Device for Shoulder Rehabilitation. Changes based on each of the reviewer’s are listed below.

1. #4 Give researchers names, contact information and affiliations in the first paragraph.

**Done – information provided in the first paragraph.**

1. #14 List risks to participants. Consent form lists fewer risks thatn “IRB Synopsis of Porposal” i.e., soreness. . . an adverse perception of their ability to movement. . . On the consent form please list the risks mentioned in the IRB synopsis form.

**Done. See section on Risks**

1. #22 and #23 How and where will sensitive dat (medical history, social security numbers, driver’s license numbers etc) be kept? Please state on consent form.

**Done. See second paragraph in section “What is Protected Health Information?”**

1. #24 consent form must state that a summary of the findings will be provided to participants upon completion of the study, if requested. Researcher should include instructions for participant with regard as to how to access results of the study.

**Done. See first paragraph in section “Contact Information – Who can you contact if you have questions, comments or complaints?”**

1. #25 IRB Approval number must be noted clearly on consent form.

**Awaiting approval number. Application ID listed at end of page 5.**

1. #31 The consent form should neither ask nor imply that subjects are waiving any rights or releasing you from liability. Under the risks section of the consent form you state that “if you are injured as a result of the research procedures, your injuries will be treated. You will be responsible for any charges.” I am uncomfortable with this statement. Why would you charge the participant if you have to treat him/her as a result of your study for which they are not compensated? That doesn’t sound right.

**This section was eliminated from the consent form.**

1. Another concern regarding this study is the fact that the participant will be asked to perform the movements/exercises of the study after their regular therapy session. Will this not be over-taxing an injured person? Would it not be safer to have the study procedure on a day with no other shoulder therapy in order to reduce the risk of soreness or injury?

**Clarification provided (see first paragraph above “Study Procedures” page 2). Subjects will perform the active movement at the beginning of the session to eliminate the possibility of soreness or effect of therapy activities.**

1. I would also emphasize the importance of safeguarding sensitive information participants submit for the study. Confidentiality and security of personal identity information once it is coded is important since the list of those sharing the study’s information is long. As mentioned above, please state where this information will be kept and will it be secure.

**Done. See second paragraph in section “What is Protected Health Information?”**

09/25/08 18:75:14

* In the consent form, page one:

“If you require further information regarding the financial arrangements described in this paragraph, you should discuss the matter with the Principal Investigator.”

It is confusing: what are the financial arrangements? It is not clearly described in any of the sections. You can either consider deleting the statements or explaining more about the financial arrangements.

**Done. State deleted.**

* On page 2: “reached a certain point the rehabilitation process.” It may be confusing to the participants? Have they reached a “bad” point or a “good” point. Please specify the sampling and selecting process in more clear terms.

**Done. Re-written to clarify procedure. Deleted the statement “reached a certain point the rehabilitation process.”**