**Reviewer 1**

11/14/10 14:03:00

A very thorough application; however there are some items on the consent form that need adjustment or additional information...

1. The title of the consent document must be “Consent Form” not “Informed Consent”. Informed consent is considered an action or an ongoing process of communication between the participant and the researcher.

This change was made on p. 1 of the Consent Form.

2. Give the researchers contact information in the first paragraph of the consent form.

A sentence was added in the first paragraph on p. 1 of the Consent Form.

3. In the Experimental Procedures/7 surveys portion of the consent form under part “e”, which is the survey about psychological distress, list at least one sample question.

An example question was added in this section on p. 3 of the Consent Form.

4. Under the risks portion of the consent form specifically state that the manual therapy, if this participant receives it could cause temporary pain and residual soreness.

A sentence was added at the end of the Risks section on p. 7 of the Consent Form.

5. A statement on the consent form that pertinent questions about the research, research participants’ rights, and/or research related injuries to participants should be directed to the IRB chair, Dr. Jon Lasser (512-245-3413) – lasser@txstate.edu, or to Ms. Becky Northcut, Compliance Specialist (512-245-2102).

This sentence was added on p. 10 of the Consent Form.

6. The location and length of time the survey data will be kept must be more explicitly stated on the consent form. You’re a little vague on this.

An estimate of the approximate time necessary to complete the surveys was added on p. 3 of the Consent Form.

7. Please state on the consent form that a summary of the findings will be provided to participants upon completion of the study, if requested. Include instructions for participants regarding how to access results of study.

This information was added on p. 10 of the Consent Form.

8. IRB application number must be on the consent form.

The IRB # was added in the header section of all pages of the Consent Form.

**Reviewer 2**

I concur with the first reviewer. In addition:

(1) CONSENT FORM

(a) Study Sponsor: May want to further clarify how the money received is being used. Especially because later on you let the participant know that they will not receive any monetary compensation.

A sentence to this effect was added on p. 1 of the Consent Form.

(b) Medical assistance: Include the statement that the participants are responsible for any medical visits/meds/procedures, etc. if a problem occurs with this study

This information was added on p. 10 of the Consent Form.

(c) Within the Consent Form, you state there will be 7 surveys. Please provide a copy of these surveys.

A copy of the surveys was added to the Protocol.

(2) HIPAA

(a) Change “informed consent form” to “consent form”. This is located on the second page, with the paragraph which starts with “This research study will involve …”

This change was made on p. 2 of the HIPAA form.

(3) IRB Application Summary

(a) You said “NO” for “asking subjects to provide Medical/health info”. HOWEVER, in HIPPA you state “This research study will involve the recording of current and/or future identifiable medical information from your hospital and/or other (e.g., physician office, physical therapy) records.” Please clarify.

The IRB application summary should have been marked as “Yes” in response to this question on the IRB Application Summary. However, all medical/health information will be self-reported by the study participant in response to the survey questions. We will not be retrieving any additional medical information from the medical record or other source.

(4) SYNOPSIS

(a) Within your Protocol, page 7, item 4.2 – change “informed consent” to “consent”

This change was made on p. 7 in addition to other instances in the Protocol where “informed consent” language was found.