-Mention is made to the surveys being mailed to researchers, but no mention is made of consent form. Also, what is methodology used to collect paperwork by center? Please have researchers expand methodology in synopsis. Expanded methods- included the separation of consent form from survey.

Consent form

-since subjects could easily assume survey is required in order to get bariatric surgery, consent form needs to explicitly state that subject will still qualify for surgery even if they choose not to complete survey. Stated that they do not have to fill out survey and the can still receive the same care from doctors.

- please ensure that consent form reads at 5th – 8th grade levels. For example, some subjects will not know what a “needs analysis” is. Please change to language similar to the following: “the information I give on the survey will be used to help determine whether an exercise program is needed for people after they undergo bariatric surgery.” Changed language

-change the first sentence of the second paragraph from “I understand that this research project is an attempt to establish the needs and desires to participate in an appropriate exercise program following surgery.” To “I understand that this research project is an attempt to establish my needs and/or desires to participate in an appropriate exercise program following surgery.” Changed language

-you say responses to survey will be anonymous. No mention as to the handling of consent forms has been made. If consent forms accompany surveys in mail, anonymity is impossible. Please explain in methodology. Explained that the surveys and the consent forms will be separated into two separate envelopes and in no particular order to protect the anonymity of the participants.

-consent form is deficient. Please refer researcher to TxState website on human subject research, where researcher will notice a document outlining guidelines for completing consent form. Please have researcher revise consent form and resubmit. Referred to guidelines

02/11/10 11:14:58

The IRB synopsis needs some work.

1. paragraph it is stated that there is little to no follow-up on this population- it is unclear if this has been reported by the surgeons of this practice or if this has been found in the literature and should be substantiated. Explained that Exercise physiologist provided the information

2) paragraph- it would more approprite to state that the subjects will not be recruited through advertisement, but will be approached during their visit to the Southwest Bariatric and that this has been approved by the practicing surgeons with a letter for verification. This permission will last for one year. Changed to this verbage

3) paragraph, EP is not defined. It is not TSU but Texas State University. Defined EP and TSU

4. Enough information is being collected that may make it possible for a person to find out the identity of the participant, therefore, all data will be secured in a locked cabinet in a locked office. Changed to this verbage

5. Our hope is that a need and desire for a . . . \'will\' be . . . and the project will be funded for futher implementation of an excercis program. Added the words will be

8., 9. 10 NA?

Consent form:

1. Spell out why the person has been chosen. (because they are considering bariatric surgery). Explained why they have been chosen

2. The project is an attempt to \'find out\' (can\'t go so far as to say establish)

3. At the end of the second paragraph, it should be stated that data will be secured in a locked cabinet in a locked office. Stated that data will be locked and stored in a locked office

4. No risks are expected, however, subjects may refuse to answer any question and may withdraw from the study at any time without any change in their care. (their standing in the University?- they are not students- right?) Changed to not completing the survey will not change their medical care.

5. They may benefit by becoming more aware of the importance of excercise to weight control. Added this

6. Participants may request findings of the study upon completion by contacting: ...Added this statement with my name and contact information

7. The amount of time for participation should be mentioned. Explianed that this would be a 1 time occurrence