

RE: NRES-D-08-00008, titled "Testing an Alternate Informed Consent Process"

I am attaching the revised manuscript. With this revised submission, I am including an itemized, point-by-point response to the comments of the reviewers. My responses to the reviewers comments are bolded.

### **Response to Reviewers:**

Reviewer #1:

1) The author(s) only cite one reference related to their statement "One of the main problems faced in conducting clinical trials is participant recruitment" (Prout, Butler, Kinnersley, Robling, Hood, & Tudor-Jones, 2003). Other authors could be cited here to indicate the degree of significance of this work. **Additional authors were cited here to support the problems with recruitment in clinical trials.**

2) Additionally, much of the research in this area has reported concerns related to recruitment of minority subjects which is not addressed here. **We agree with the reviewers concerns related to recruitment of minority subjects. Because this study used a convenience sample of current cardiac rehabilitation participants in an academic medical center in the Midwest, we had limited minority subjects to try and recruit into the study. Because only one minority subject participated in the study, it would have violated confidentiality to present the results of this one person as his/her results could not be presented in aggregate and he/she would be easily identifiable in the manuscript. Being able to include only one minority patient in the study was a definite limitation of the study. Information was added to the article about strategies that were effective in recruiting minority subjects in earlier research and that additional research is needed to identify additional strategies to recruit these individuals.**

3) The author(s) could use literature from bioethics which identifies issues related to informed consent in research. **Other literature related to informed consent was added.**

4) Also, in light of the mean age of subjects (N = 61), it might be worth highlighting research in the elderly and strategies on informed consent in this population. **Strategies used in engaging elderly in research were added to the discussion section of the manuscript.**

5) Although the authors indicate that this was a nonprobability survey design, it is not clear how the author(s) determined 35 subjects would be appropriate and what was the expected percent increase in response rate that they were estimating, if any. I am assuming that this was another pilot study given the first feasibility study and low participation rate, but the authors should clarify. **Because this study was an offshoot of the first feasibility study, we enrolled the sample (n=35) that we were able to obtain within the limited time and resources that we had to conduct the study. We expected an increase in the enrollment rate over the earlier feasibility study but we did not have an a priori level of increase specified. For this revision, we did compute the**

**statistical difference between the proportion of subjects enrolled in the first and second studies and added this finding to the manuscript to strengthen it. This alternate consent process resulted in an enrollment rate nearly 2.5 times the previously obtained rate, a statistically significant increase ( $X^2[1] = 14.52, p < .001$ ).**

6) Demographics are presented as were the increase in response rate of participants. The authors stated that "In response to the flip chart, participants overwhelmingly stated that it was informative, helpful, explained the study well, and that the photographs were effective in communicating the purpose of the study." What percent of subjects here indicated this? **In the study, 89% of the participants indicated that the flip chart was helpful. This information was added to the results section of the manuscript.**

7) The majority of the subjects in this study were White and educated but the authors do address limitations of their study and tie the literature nicely to their purpose. I might also add a sentence or two related to informed consent in the elderly population given your mean age group of 62. **We added information in the discussion section about strategies that are effective in recruiting the elderly during the informed consent process.**

Reviewer #2:

1) On pg 2, line 9, I would eliminate the word, "previous" in that it is initially unclear to the reader if the feasibility study is the same one described in the immediately preceding paragraph (I assume that it is). **Yes, this was changed as recommended.**

2) On pg 5, line 12, I would change the word, "current" to "earlier". **This was changed as recommended.**

3) On page 7, I suggest moving the sentence beginning at the end of line 5 and ending in the middle of line 8 to the middle of line 12 after the word, "survival". In short, summarize the barriers to cardiac rehabilitation research first and then summarize the barriers to clinical trials. **This was changed as recommended.**

4) Even though it is not the primary point of the current article, I wondered if the home-based cardiac rehabilitation would be monitored. **The home-based participants were loaned a polar watch during the study to monitor their heart rate during exercise. No other monitoring of the heart rate or rhythm was done for the home-based group due to the expense. No information about the monitoring was added to the manuscript as it might detract from the main purpose of the article.**

In addition, the references were checked and for APA formatting issues (e.g., for 6 or more authors, use only the first author's name with et al. [i.e., Prout et al., 2005]). Figure 1 was cited in the text and we changed the fonts in Figure 1 so that it was more legible.

Thank-you for the comments and helpful feedback in the resubmission of this manuscript.

