IRB application # 2010W1368- Response to IRB Committee suggestions and concerns.

1. Reviewer #1  
   01/07/10 08:35:55   
   Almost everything seems in good order for this application IRB# 2010W1368. Two additional requirements should be added to the consent form:
   1. 1)State clearly on the consent form that the money earned from participation is only given in a lump sum at the end of the study. I am unclear about that. You mention $10 per session. The participant might expect a portion if he or she drops out. Perhaps just drop the $10 per session reference.
      1. **Response: Phrase about $10 per session has been dropped.**
   2. 2)Add a sentence to the consent form about how the participant might access the results of the study. Your statement \"Upon completion of the study, all participants will be given the opportunity to participate in the program again if study results indicate possible rehabilitation benefits\" doesn\'t quite satisfy the access of findings requirement.
      1. **Response: Sentence added that the participant might contact the researchers to get a copy of study results.**
2. #2  
   01/11/10 12:19:57   
   A few clarifications in consent form would improve comprehension by participants:
   1. 1) cognition in paragraph on purpose could be changed to \'ability to understand\'
      1. **Response: Phrase changed**
   2. 2) under testing procedures: \'which quantify\' could say describe a numberical value.
      1. **Response: Scores added**
   3. 3) compensation should actually be given throughout the study to comply with regulations to allow participants to leave the study without being penalized.
      1. **Response: verbiage now indicates that participants will be compensated according to their participation level which is not a penalty.**
   4. 4) data are saved in a locked cabinet - should also say in a \'locked office\' to comply with double lock standard.
      1. **Response: Phrase added**
   5. 5) Typically there should be a way for participants to find out the outcome of the study after it is completed and they should know that their information data will be reported but not identified with them (or only composite info reported)
      1. **Response: Sentence changed to include report of composite information.**
   6. 7)no alternate treatment is mentioned - if there is no other alternate treatment that should be stated.  
      IN proposal
      1. **Response: This is project which includes a series of 3 testing sessions which may result in a treatment effect however it should not be viewed as a primary treatment project. Therefore, no alternate treatment is being offered in parallel with testing sessions.**
   7. 8) vestibular ocular reflex is not explained in terms easily understood - in proposal
      1. **Response: The explanation of the vestibular ocular reflex is provided in the consent form’s phrase “your dynamic vision will be assessed to see how well you can see while your head is moving.” We do use the technical terminology to keep language around a 8-9th grade level of understanding.**
   8. 9) optotype E is not explained- in proposal
      1. **Response: The explanation of the optotype E is provided in the consent form phrase: “You will be asked to move your head and tell what direction the letters are oriented on the computer screen.”**
   9. 10) Because there is no random sampling or assignment, it might strengthen the results to have a larger sample size- (even after power analyses).
      1. **Response: We appreciate the suggestion of larger sample size however this is a pilot study which explores repeated measures of the 20 participants A power analysis (Power and Precision vs. 3.0) was conducted with a sample size of 20 subjects (10 per group) using criterion for significance of a power of 80% and an alpha 0.05, for a 2-tailed test. Specifically, assuming the mean group outcome differences at 0.5 -1.5 times the standard deviation (approximate 12% difference), we will need 8 per group. The interaction between the within and between group factors will achieve 76 – 82%*. A Geisser-Greenhouse Corrected F Tests is assumed to be used.***