

Dear Clinical Trials SIG,

Please review the attached documents before the SIG meeting at 11 am this Friday, November 18, 2011 in the China Basin Library:

- 1) Katzman RO1 revised Protection of Human Subjects section
- 2) Vittinghoff & Hulley DSMB Charter Attachment D: Guidelines for recommendation of continuation, modification, or stopping the VEST study
- 3) Drazen & Wood, Don't Mess with the DSMB. NEJM 2010;363:477-8

At our meeting I would like feedback about my responses (in track changes in attachment 1) to the summary statement comments on my recent RO1 application to the National Institute of Aging. Here's what the Summary Statement said:

"PROTECTIONS FOR HUMAN SUBJECTS: UNACCEPTABLE

"Eligibility criteria are not sufficiently defined to ensure that the participants will be healthy enough to engage in high-intensity exercise training. There was no consideration as to whether high-intensity exercise could cause harm in individuals who have spinal deformity, in some cases secondary to vertebral fractures."

I am resubmitting the grant December 2, so I am very interested in your feedback.

In addition, attachments 2 and 3 will serve as a springboard for what I hope will be a hearty discussion about other aspects of fulfilling our responsibility to protect human subjects in clinical trials. I also welcome contributions by other SIG members to our seminar on DSMB issues.

Best,
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