From: <u>Hudes, Estie</u>
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Subject: next Methods Core seminar: 10/23/18; Steve Gregorich, PhD -- "Controversies and Unresolved Issues in the Design of Randomized

Controlled Trials Testing Clinical/Behavioral Interventions"

Date: Monday, September 17, 2018 7:58:43 PM

Dear Methods Core seminar participants,

This announcement is for our October seminar.

<u>Title</u>: Controversies and Unresolved Issues in the Design of Randomized Controlled

Trials

Testing Clinical/Behavioral Interventions

Presenter: Steve Gregorich, PhD

Department of Medicine & Department of Preventive and Restorative Dental

Sciences, UCSF



Date: Tuesday, , October 23, 2018

<u>Time</u>: 11 am - 1:00 pm

Location: AmfAR Conference room MH-3700

550 16th Street (at 4th Street), 3rd Floor

Mission Bay, SF 94158

<u>Abstract</u>: Within the context of an efficacy, effectiveness, or implementation science trial (RCT), many clinical/behavioral trialists insist that optimal study designs require (i) intervention and control groups that are matched with respect to the amount of time and attention required of study participants and (ii) adjustments to alpha levels for 'multiple

comparisons.' Other clinical/behavioral trialists argue that (i) a 'usual care' control group design often is best and (ii) adjustments for 'multiple comparisons' are unnecessary and undesirable. In this talk, I detail scientific, policy-related, and ethical arguments for the superiority of the latter perspective. Additionally, some scientists contend that pilot trials, in part, are intended to yield an effect size estimate that will inform a power analysis supporting the design of a future full-scale RCT, whereas others argue that pilot trials should limit their focus to evaluating acceptability and feasibility of the intervention and study procedures. The latter viewpoint is the correct one, but raises a question about how to determine the appropriate effect size estimate to use in a power analysis. We will discuss related issues including implications for obtaining research funding and publishing results from RCTs.

Short Bio: Steve's research focuses on disease prevention and preventive health behaviors within diverse populations. His 24-year career includes over 75, largely federally funded, research projects, centers, and career development awards. Relevant to this talk, he has served as principal statistician and/or data coordinating center director of 20 large-scale randomized controlled trials testing behavioral/clinical interventions.

Please let <u>Estie Hudes</u> know if you are planning to attend the seminar and, if you are coming from outside of Mission Hall, whether you need to be put on the building security list.

Hope to see you many of you on October 23.
Estie

For building entrance at Mission Hall., please RSVP to Estie Hudes ahead of time.

Future Methods Core seminars can be checked at: https://prevention.ucsf.edu/upcoming-events

The CAPS Methods Core activity, as well as material from past seminars, can be checked directly at: https://prevention.ucsf.edu/about/caps-structure-and-cores/methods-core/methods-core-seminars

Directions to Mission Bay:

http://campuslifeservices.ucsf.edu/transportation/services/alternative_transportation/mission_bay_transit_options
Please note that you can only use the Red shuttle at 16th Street BART if you have a current UCSF ID badge,

Parking at Mission Bay: http://campuslifeservices.ucsf.edu/transportation/services/parking/public_parking http://campuslifeservices.ucsf.edu/transportation/services/parking/public_parking http://campuslifeservices.ucsf.edu/transportation/services/parking/public_parking

Specialist / Statistician

Center for AIDS Prevention Studies (CAPS): https://prevention.ucsf.edu/

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