# Getting SMART about Developing Individualized, Adaptive Health Interventions: An Introduction to a Novel Experimental Study Design

**Baltimore, Maryland – Tuesday, February 26, 9:00AM-1:00PM**

**Instructor: Daniel Almirall (Univ. of Michigan)**
**Organizer: Seth Himelhoch (MIRECC / Univ. of Maryland Medical Center)**

| Module | Time | Topic |
|---|---|---|
| **MODULE 1** | **09:00-9:50AM (50 min)** | **Introduction to Adaptive Health Interventions**<br>• What are adaptive health interventions (AHI)?<br>• What are the pieces that make up an AHI?<br>• Compare simple versus deeply-tailored AHIs.<br>• Discuss why AHIs are needed<br>• Utilizing theory to design an AHI<br>• How AHIs can be used to inform clinical practice |
| **Q&A** | **9:50-10:15AM (25 min)** | **Question, Answer & Discussion about Adaptive Health Interventions** |
| **MODULE 2** | **10:15-11:05AM (50 min)** | **Sequential Multiple Assignment Randomized Trials (SMARTs)**<br>• What are SMARTs?<br>• Why do we need SMARTs?<br>• Discuss SMART design principles.<br>• What are typical primary and secondary aims in a SMART?<br>• How do SMART designs differ from standard randomized clinical trial designs? |
| **Q&A** | **11:05-11:30AM (25 min)** | **Question, Answer & Discussion about SMART Designs** |
| **LUNCH BREAK** | **11:30-12:00** | **Very Brief Lunch** |
| **MODULE 3** | **12:00-12:45PM (45 min)** | **Case Studies: SMART Studies Completed or in the Field**<br>• Give examples of SMARTs used to develop AHIs, that are completed or currently in the field<br>• Examples to be covered: Autism, child ADHD, women who are pregnant and abuse substances, adult alcohol use |
| **Q&A** | **12:45-1:00PM (15 min)** | **Question, Answer & Discussion about SMART Case Studies** |

In this workshop, we will cover the basics of Adaptive Health Interventions and SMART design. The material we cover is intended to help investigators become familiar with the basic methodology, including the rationale for a SMART and the types of scientific questions that can be answered using SMART. This should provide the necessary background for investigators to propose a SMART study (e.g., grant) of their own. Each module builds on the previous one; therefore, it is highly recommended that investigators participate throughout the entire workshop. Due to time limitations, we do not

cover in depth how to analyze data arising from SMART; however, much of this additional material is available on Daniel Almirall's website (http://www-personal.umich.edu/~dalmiral/ ) or the Methodology Center at Penn State University (http://methodology.psu.edu/ ). Helpful references are given on the next page.

# List of References for Adaptive Health Interventions and SMART


L.M Collins, S.A. Murphy and K.A. Bierman (2004), A Conceptual Framework for Adaptive Preventive Interventions, *Prevention Science* 5:185-196.

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A.I. Oetting, J.A. Levy, R.D. Weiss, S.A. Murphy (2011), Statistical Methodology for a SMART Design in the Development of Adaptive Treatment Strategies,, *Causality and Psychopathology: Finding the Determinants of Disorders and their Cures,* (P.E. Shrout, K.M. Keyes, K. Ornstein, Eds.) Arlington VA: American Psychiatric Publishing, Inc, pgs. 179-205

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Almirall D., Compton S.N., Gunlicks-Stoessel M., Duan N., Murphy S.A. (accepted 2011; to appear). *Preparing for a Sequential Multiple Assignment Randomized Trial for Developing an Adaptive Treatment Strategy: Designing a SMART Pilot Study.* Statistics in Medicine, Vol 31, No. 17. *To appear: Meanwhile, obtain a copy of an older Technical Report from the Methodology Center at Penn State University.*

Almirall D., Compton S.N., Rynn M.A., Walkup J.T., Murphy S.A. (accepted 2012; in press). *SMARTer Discontinuation Trials: With Application to the Treatment of Anxious Youth.* Journal of Child and Adolescent Psychopharmacology. *To appear: Meanwhile, obtain a copy of an older Technical Report from the Methodology Center at Penn State University.*