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## **Symposia**

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## Overview

With the assistance of experts from several NIH ICs, the Office of Behavioral and Social Sciences Research (OBSSR) has organized a series of symposia to provide NIH staff with expertise relevant to randomized clinical trials (RCTs) with behavioral interventions. The series assumes the audience has basic or general understanding of RCT design and implementation. The emphasis is on issues of particular concern to RCTs in which the intervention (i.e., “treatment”) is behavioral, whether alone or in combination with biomedical treatments. (The outcomes may be behavioral or biomedical.) These issues may or may not be unique to behavioral RCTs (i.e., quantitative vs. qualitative differences in the nature of behavioral vs. biomedical RCTs).

## Learning Goals

The overall goals of the series of symposia are to provide sufficient information so that participants will be able to:

- Describe the principles underlying the conduct of unbiased clinical trials.
- Contrast biomedical vs. behavioral interventions in the context of RCT
- Evaluate and interpret critically the literature on RCTs for behavioral interventions.
- Contrast and evaluate alternative research designs in terms of their appropriateness.
- Contrast and evaluate methods for monitoring, coordinating, and conducting RCTs.
- Select appropriate outcome measures, enrollment strategies, and randomization techniques.

## Recommended Textbook

Lawrence M. Friedman, Curt D. Furberg, and David L. DeMets, *Fundamentals of Clinical Trials*, Third Edition. New York: Springer-Verlag, 1998.

## Contacts for Information

### *Logistical and Administrative Questions*

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### *Course Content and All Other Matters*

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## Symposia: Topics,\* Schedule, and Faculty

### ***I. Introduction***

Lynda Powell and Peter Kaufmann

January 10, 2003, 9:00-11:00 AM

Natcher Conference Center, Rooms E1-E2

*Rationale for the course.*

Brief overview of the subject matter to be covered. What do behavioral and biomedical (non-behavioral) trials have in common and how do they differ? What are some of the issues that the course will address?

### ***II. Design Issues***

Part A:

Frank Keefe and Sheryl Kelsey

February 13, 2003, 10:00 AM to 12:00 PM

Natcher Conference Center, Rooms E1-E2

*Small vs. large (single vs. multiple sites).*

How does size relate to the research question? What are the advantages and disadvantages of small vs. large-scale studies, where size is defined in terms of number of participants and/or number of performance locations. When is the right time for large, multi-site studies? When is a large study not appropriate?

- *Complexity of study design:* Can “complex designs” be carried out successfully in large-scale studies? What is meant by “complex” designs? Mixed methods.
- *Combining behavioral and biomedical interventions:* Appropriate designs. When is too much being measured and participant burden is too high?

*Randomization.*

How to decide on the unit of randomization: individuals vs. groups (e.g., classrooms, communities)? What are the benefits and downsides to each?

\* The specifics of each session are likely to vary from the exemplary topics listed here.

## Part B:

Frank Keefe and Karina Davidson

February 13, 2003, 1:30 to 3:30 PM

Natcher Conference Center, Rooms E1-E2

### *Control groups vs. comparison groups.*

What is the importance of generating allocation sequences and concealment of allocation? Are randomization and masking possible in trials with behavioral interventions? What are the difficulties in operationalizing behavioral “placebos?”

- *Masking (“blinding”) of Assignment:* Are there problems particular to behavioral interventions?

### *Internal and external validity.*

Does tight experimental control limit generalizability of the results? Is there a trade-off between internal and external validity? How are they obtained in research designs?

### *Efficacy vs. Effectiveness.*

What is the difference? Is this a meaningful distinction? What does this difference mean in terms of site selection, recruitment, protocol development, protocol adherence, assessment of outcomes/endpoints, analyses, inferences, and applications to practice? When should one approach be chosen over another? What factors preclude or obstruct each approach? Can power and sample size be estimated for effectiveness trials when so many variables are uncontrolled? If so, how? What are practical implications? What role does preference have in trial design?

### **III. Sample Characteristics, Recruitment, and Maintenance**

Janet Wittes and Lynda Powell

March 3, 2003, 3:00 to 5:00 PM

Natcher Conference Center, Balcony B

#### *Defining the sample and its size.*

Inclusion and exclusion criteria. What population does a sample represent? Single vs. multiple sites. Threats to external validity.

- *Power analysis and sample size:* How to estimate effect sizes? What is an “important” vs. statistically significant difference?

#### *Recruitment.*

How can recruitment potential be assessed based on population in the catchment area and investigator experience and performance? How can we assess ability to be successful in minority recruitment? How can participation rates be maximized, especially among minority or underserved populations? What is the appropriate role of incentives? What recruitment strategies work and for whom? When should one reassess and reformulate a recruitment strategy (during the course of the RCT)?

#### *Preventing Attrition.*

Participant loss and implications for analyses and inference. Methods for minimizing sample attrition; analyses of loss to follow-up. Differential attrition across sites and/or over time.

- *Site Attrition:* How to minimize the risk of losing one or more sites? What can be done if a site is lost?

## **IV. Outcome Measures**

Robert Kaplan and Nina Schooler

April 28, 2003, 9:00 to 11:00 AM

Natcher Conference Center, Rooms E1-E2

### *Intermediate and ultimate outcomes.*

Categories or kinds of outcome measures: Psychological, behavioral, functional and quality of life, physiological. Which are appropriate? Under which circumstances? Relative advantages and disadvantages (e.g., self-report vs. chemical assays)?

### *Construct validity of scales and linear aspect.*

Use of standard scales vs. new, specially designed scales: Is it time to redo scales using measurement principles and past experience? Scaling to increase the range or dispersion of responses? How do we measure personal performance and social outcomes? How can duration of effects be assessed when considering outcomes relevant to chronic conditions? How does this differ from short-term assessments?

### *Mediating variables.*

Evaluation of implementation, impact on hypothesized mediators of effects (as opposed to endpoints or outcomes) and the relationships among these levels. How and when should we measure contribution of social and cultural context in facilitating outcomes (i.e., use as covariates, controls vs. process variables)? Models for testing mediation and moderation of outcomes.

### *Cost effectiveness.*

When are cost effectiveness analyses appropriate? What are the elements of accurate and useful cost-effectiveness analyses?

## **V. Management and Administrative Issues**

William Harlan and Denise Simons-Morton

May 2, 2003, 3:00 to 5:00 PM

Natcher Conference Center, Rooms E1-E2

*Problems (e.g. management, quality control, lagging recruitment, data entry).*

Potential problems and how to avoid them. How do we measure exposure to treatment and quality at sites? Is a site covariate adequate in analyses? Can assessment of intermediate measures monitor poor performance? What is the role of “interim looks?” Multi-site vs. single site studies.

*Assessing and maintaining treatment fidelity.*

Across sites, overtime. Initial training and adherence to treatment protocols by investigators and research participants (subjects).

*Budget development models.*

Generic template method vs. individual budgets; paying per subjects vs. a flat rate for all sites regardless of number recruited.

*Ancillary studies.*

When are they appropriate? What are the pros and cons?

*Data safety and monitoring.*

New NIH requirements and their implementation. Stopping an intervention.

*Ethics issues.*

Informed consent; certificates of confidentiality; genetic testing; unblinding.

*Role of NIH staff.*

In grants vs. cooperative vs. contracts. Scientific vs. administrative roles.

## **VI. Analytic Methods**

Janet Wittes and Michael Proschan

June 6, 2003, 3:00 to 5:00 PM

Natcher Conference Center, Rooms E1-E2

### *Change and group differences.*

Advantages of various approaches to analyses for measurement of change.

### *Intention to treat vs. As Treated Analyses.*

### *Analysis of group randomized trials.*

Issues for studies in which units other than the study participants, such as schools or communities, are randomized, requiring special design and analytic considerations.

### *Missing data.*

Implications and approaches to analysis.

- *Cross-over and loss to follow-up*

### *Alternative approaches.*

Life table methods, multiple event analyses; structural equation modeling; growth modeling; composite scores.

### *Interim Analysis.*

How to plan in advance and when are they appropriate?

### *Uninterpretable results.*

Minimal differences among treatment groups and/or control groups. Potential causes (e.g., poor quality of measurement, low adherence)? How interpret? For example, problem of secular trends (e.g., behavior change in general population and thus in control/comparison groups). Placebo effects.

### *Subgroup and Secondary Analyses.*

The need to plan for analyses before the clinical trial begins. When are they valid and what inferences can be made? Data dredging vs. hypothesis generation.

## Faculty

### **Dr. Karina Davidson**

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## Faculty Biographical Statements

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Dr. Davidson is Assistant Professor of Medicine and Clinical Intervention Research Director of the Integrative and Behavioral Cardiology Program at the Zena and Michael Wiener Cardiovascular Institute of the Mount Sinai Medical Center in New York. Dr. Davidson's research focuses on the interplay between personality, emotions, and physical indices of health in adults. Cardiovascular diseases comprise the area of physical health that she typically studies, and she is interested in personality assessment and intervention at the primary, secondary, and tertiary stages of these diseases. She has conducted randomized controlled trials primarily in anger management, but has recently developed an interest in depression reduction and subsequent improvement in cardiovascular parameters such as uncontrolled hypertension and silent ischemia. Of note are her two randomized controlled trials demonstrating that anger expression changes, gained from group therapy, decrease hostility as well as blood pressure and hospital re-admissions. Dr. Davidson is the Chair of the Society of Behavioral Medicine Committee on Evidence-based Behavioral Medicine, a task force charged with improving and implementing evidence-based principles for behavioral medicine researchers, practitioners, and students. She has taught evidence-based psychotherapy theory and practicum courses to clinical psychology graduate students for a number of years at both the University of Alabama and Dalhousie University. She is an editorial board member of *Psychosomatic Medicine and the Journal of Research in Personality*.

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Dr. Kaplan is Professor and Chair of the Department of Family and Preventive Medicine, at the University of California, San Diego. He is a past President of several organizations, including the American Psychological Association Division of Health Psychology, Section J of the American Association for the Advancement of Science (Pacific), the International Society for Quality of Life Research, and the Society for Behavioral Medicine. He is currently Chair of the Behavioral Science Council of the American Thoracic Society and President of the Academy of Behavioral Medicine Research. Dr. Kaplan is the Editor-in-Chief of the *Annals of Behavioral Medicine*, Associate Editor of the *American Psychologist*, and Consulting Editor of four other academic journals. Selected additional honors include APA Division of Health Psychology Annual Award for Outstanding Scientific Contribution (For junior scholar 1987 and again for a senior scholar 2001), Distinguished Research Lecturer, 1988, and Health Net Distinguished Lecturer in 1991, University of California 125 Anniversary Award for Most Distinguished Alumnus, University of California, Riverside, American Psychological Association Distinguished Lecturer, and the Distinguished Scientific contribution award from the American Association of Medical School Psychologists. His public service contributions include various NIH, AHRQ and VA grant review groups, and service on the local American Lung Association (ALA) Board of Directors and the regional research committee for the American Heart Association. He has served as co-chair of the Behavioral Committee for the NIH Women's Health Initiative, and a member of both the NHLBI Behavioral Medicine Task Force and the Institute of Medicine (IOM) National Academy of Sciences Committee on Health and Behavior. In addition, he is the chair of the Cost-/Effectiveness Committee for the NHLBI National Emphysema Treatment Trial (NETT). Dr. Kaplan is the author or co-author of more than a dozen books and more than 350 articles or chapters.

*Peter G. Kaufmann, Ph.D.*

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Dr. Kaufmann is Leader of the Behavioral Medicine Research Group at the National Heart, Lung, and Blood Institute (NHLBI), NIH. He was educated at Loyola University (Chicago) and the University of Chicago, followed by postdoctoral research at Duke University. He was involved in several multi-center randomized clinical trials involving behavioral interventions, including the Hypertension Intervention Pooling Project, Trials of Hypertension Prevention, the Raynaud's Treatment Study, and Enhancing Recovery in Coronary Heart Disease patients.

Francis J. Keefe, Ph.D.

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Dr. Keefe is a Professor of Psychiatry and Behavioral Sciences and Associate Director for Research in the Duke Pain and Palliative Care Initiative at Duke University Medical Center. In addition, he is a Professor of Psychology: Social and Health Sciences at Duke University. He received his undergraduate degree in psychology at Bowdoin College (B.A., 1971) and his Ph.D. in Clinical Psychology at Ohio University (Ph.D., 1975). Following graduate school he completed a Post-Doctoral fellowship in the Psychophysiology Lab at Massachusetts Mental Health Center at Harvard Medical School, where he conducted research on clinical applications of EMG biofeedback. Dr. Keefe has broad interests in behavioral and psychological aspects of pain and pain management. He is recognized for his research on pain coping and his controlled treatment outcome studies evaluating the efficacy of coping skills training interventions for persons suffering from persistent disease-related pain. Dr. Keefe has played a key role in the development of clinical pain services and pain research programs at Duke Medical Center. For 20 years he directed the Pain Management Program and was a leader in the development of Duke Medical Center's multidisciplinary pain programs (both out-patient and in-patient). He has developed and refined a number of treatment protocols for persistent pain including spouse- and partner-assisted pain coping skills training interventions. After spending a year-and-a-half on the faculty of his alma mater (Ohio University), Dr. Keefe returned to Duke in the Fall of 1999 to take a position as Associate Director for Research in Duke's new Pain and Palliative Care Program. He is currently an Associate Editor for the *Journal of Consulting and Clinical Psychology*. He also serves as Secretary of the American Pain Society and Psychology Section Editor for the journal *Pain*. Dr. Keefe is a fellow of the Division of Health Psychology and of the Society of Behavioral Medicine. He has been active in the Society of Behavioral Medicine and the International Association for the Study of Pain. He has published over 140 papers, 42 book chapters, and three books on topics ranging from pain during mammography to the assessment of cancer pain. In recognition of his clinical research, Dr. Keefe was recently awarded the Wilbert Fordyce Clinical Investigator Award at the American Pain Society. He has served on numerous NIH Study Sections including the Behavioral Medicine Study Section and is frequently asked to consult with NIH program staff and other government programs (e.g., Department of Labor). Dr. Keefe recently completed his terms as an Associate Editor for *Health Psychology*. He has frequently served as a member of the Division 38 Scientific Program as a reviewer.

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Dr. Kelsey, Professor of Epidemiology, is a statistician and Co-Director of the Epidemiology Data Center, Graduate School of Public Health, University of Pittsburgh. The Epidemiology Data Center has a 20-year history and employs over 100 faculty, staff and students. She and her colleagues coordinate multicenter clinical trials and registries primarily in cardiology, but also in liver transplantation, neurology, psychiatry, and ophthalmology. Dr. Kelsey's career has focused on design, coordination and analysis of clinical trials, and she has served as Principal Investigator or Co-Principal Investigator for coordinating centers for a number of National Institutes of Health-sponsored multicenter clinical trials. For 10 years she has taught a class in design of clinical trials. She has also taught a class in controversies in clinical trials that includes examination of behavioral clinical trials and alternative and complimentary medicine clinical trials. Dr. Kelsey has served on over a dozen Data and Safety Monitoring Boards for the National Institutes of Health, the Veterans Administration, and in industry.

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Dr. Powell is a Professor of Preventive Medicine and Psychology and the Director of the Division of Population Sciences and the Section of Epidemiology in the Department of Preventive Medicine. She is a licensed clinical psychologist and a psychosocial and cardiovascular epidemiologist with expertise in anger/hostility, social support, spirituality, depression, ovarian function, and alcohol consumption—and their relationship to cardiovascular disease, particularly in women. Dr. Powell received her graduate training in psychology at Stanford University and her post-graduate training in epidemiology and biostatistics at Mt. Zion Hospital of the University of California at San Francisco. She has expertise in clinical trial methodology and was formerly the Principal Investigator of the Chicago site of the Enhancing Recovery in Coronary Heart Disease program, a multicenter randomized behavioral clinical trial aimed at treating depression and low social support in patients with new myocardial infarction. She is currently the Principal Investigator of HART, a randomized behavioral clinical trial of 900 patients with heart failure aimed at teaching self-management skills. She also has expertise in observational epidemiology and is currently the Principal Investigator of 3 longitudinal, population-based studies of psychosocial and sub-clinical cardiovascular changes that occur as women undergo the menopausal transition. Dr. Powell is a Co-Principal Investigator of the Chicago site of the Women's Health Initiative, where she sits on the Behavioral Advisory Committee that guides all behavioral aspects of the clinical trials and the observational study including strategies to improve adherence and retention. She is the Principal Investigator of the Chicago site of two WHI ancillary clinical trials that are exploring the impact of hormone therapy on cognition in post-menopausal woman.

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Dr. Proschan received a Doctorate in Statistics from Florida State University in 1989, a Master of Science in Statistics from Stanford University in 1982, and a Bachelor of Science in Statistics and Mathematics from Florida State University in 1980. Since 1989, Dr. Proschan has been a Mathematical Statistician at the National Heart, Lung, and Blood Institute. He has worked on several clinical trials that used behavioral or non-pharmacologic interventions such as diets and lifestyle changes. His role in these trials has been to help with design (sample size/power, whether to pair-match, whether to use a parallel-arm or crossover trial, etc.) and analysis issues (what kind of model to use, handling missing data, etc.). Dr. Proschan is also involved in smaller clinical trials and other kinds of studies, such as measuring agreement between real-time 3D echocardiography and angiography with respect to whether segments of the heart are diseased. His responsibilities also include methodological research; he has a special interest in research on adaptively modifying sample size in clinical trials. He taught statistics and mathematics courses at Palm Beach Junior College, Tallahassee Community College, Florida State University, and Stanford University. More recently, Dr. Proschan taught a course called Methodology in Clinical Trials for the Foundation for the Advancement of Education in the Sciences. Before becoming involved in biostatistics, Dr. Proschan was an engineering statistician at Pratt and Whitney Aircraft, which makes engines for commercial and military airplanes. He conducted risk analyses, modeled failure times, and worked on tolerance problems, among other duties.

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Dr. Schooler is the Director of Psychiatry Research at the Hillside Hospital Division of the North Shore Long Island Jewish (NSLIJ) Health System. She received her Doctoral degree from Columbia University in social psychology in 1969. She held a number of positions in the Extramural Programs of the National Institute of Mental Health (NIMH), where she not only administered grant programs and grant review, but also designed, directed, and coordinated multicenter clinical trials of both medication and psychosocial treatments for schizophrenia. She left the NIMH to become Professor of Psychiatry at the University of Pittsburgh School of Medicine. She has continued to focus her research on both schizophrenia and multicenter trials at the University of Pittsburgh and more recently at Hillside Hospital, where she is the Associate Director of an NIMH-supported Intervention Research Center for Schizophrenia. Her contributions to clinical trial methodology include instrument development for assessment of adverse effects, social adjustment and psychopathology. She has edited books and written about controlled clinical trials in clinical psychology and psychiatry. She has also been an active participant in the ongoing developments designed to enhance protection of potentially vulnerable populations who participate in research. Dr. Schooler is actively developing methods to assess patient understanding of research participation.

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Janet Wittes, Ph.D. is the President of Statistics Collaborative, Inc. She is a member of many advisory committees, including a large number of Data and Safety Monitoring Boards (DSMBs) for randomized clinical trials sponsored by both industry and government. Among other positions, she has served as Chief of Biostatistics Research Branch, National Heart, Lung, and Blood Institute. Her research has focused on the design and analysis of randomized clinical trials. She is a Fellow of the American Statistical Association and the American Association for the Advancement of Science and an elected member of the International Statistical Institute. She is a past President of The International Biometric Society – Eastern North American Region (1995) and The Society for Clinical Trials (2001). From 1990 through 1995 she served as the Editor-in-Chief of *Controlled Clinical Trials*. She received her A.B. in Mathematics from Radcliffe College (1964) and her Ph.D. from the Department of Statistics of Harvard University (1970).

## NIH Organizing Committee

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## Application for Continuing Education Credits

The National Institutes of Health (NIH) is approved by the American Psychological Association to offer continuing education for psychologists. The NIH maintains responsibility for the program. The National Institutes of Health/Foundation for Advanced Education in the Sciences is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.

The National Institutes of Health also designates this activity for a maximum of 14 hours of credit for APA Continuing Professional Education. Each eligible participant should claim only those hours of credit that he/she actually spent in the educational activity. The National Institutes of Health/Foundation for Advanced Education in the Sciences designates this educational activity for a maximum of 14 hours in Category 1 credit towards the AMA Physician's Recognition Award.

To obtain certification of attendance, please complete this form. Be sure to specify which kinds of credits (i.e., APA and/or AMA) you are requesting. You may leave it at the continuing education table at the conclusion of the symposium series or mail the form to:

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## Daily hours attended

I affirm that I have attended the following session(s) of the *NIH Symposium Series on Issues in Randomized Clinical Trials Involving Behavioral Interventions*:

Date	Maximum Program Hours Eligible for CME/CPE	Hours attended (CME/CPE Claimed)
Introduction January 10, 2003	2	
Design Issues, Part A February 13, 2003	2	
Design Issues, Part B February 13, 2003	2	
Sample Characteristics, Recruitment, and Maintenance March 3, 2003	2	
Outcome Measures April 28, 2003	2	
Management & Administrative Issues May 2, 2003	2	
Analytic Methods June 6, 2003	2	
<b>Total</b>	<b>14</b>	

Please complete the form by printing your details and mail to:

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<b>Type of Certificate Requested:</b>		<b>American Psychological Association</b>		<b>Continuing Medical Education</b>	
<i>Please circle to specify:</i>		Yes	No	Yes	No
Name-Last	First	Middle Initial	Professional Degree	Date of Birth (month/day/year)	
Phone	E-mail	Fax	Institute/Center	Branch/Section	
Building, Room, Street Address, and MSC					
City		State		Zip Code	

## Disclosure to Audience

### *NIH/FAES Full Disclosure of Speaker Financial Interests or Relationships*

The Accreditation Council for Continuing Medical Education (ACCME) requires that any speaker who makes a presentation at a program designated for AMA Physician's Recognition Award (PRA) category 1 credit must disclose any significant financial interest or other relationship that speakers may have with the manufacturer(s) of any commercial product, service, technology, or program discussed in their educational presentation. It is also required that each speaker disclose to the audience any discussion of an unapproved/investigative use of a commercial product/device. Furthermore, speakers are asked to disclose relationships with the Office of Behavioral and Social Sciences Research, Office of the Director, NIH, which is the financial supporter of the lecture series.

The ACCME does not imply that such financial interests or relationships are inherently improper or that such interest or relationships would prevent the speaker from making a presentation. It is imperative, however, that such financial interests or relationships be identified by the speaker so that participants at the CME activity may have these facts fully disclosed prior to the presentation, and may form their own judgments about the presentation.

In keeping with this policy, the NIH/FAES CME Committee requires the speaker complete and sign this form. The following chart summarizes the responses of the speakers in the RCT Symposium Series. Copies of responses from specific speakers are available upon request.

Speaker	Off-label, unlabeled investigative use	Consultant or Lecturer	Grant or Research Support	Other	Speakers Bureau	Stockholder
Ronald Abeles	None	None	None	None	None	None
Karina Davidson	None	None	None	None	None	None
William Harlan	None	None	None	None	None	None
Robert Kaplan	None	None	None	None	None	None
Peter Kaufmann	None	None	None	None	None	None
Frank Keefe	None	None	None	None	None	None
Sheryl Kelsey	None	None	None	None	None	None
Lynda Powell	None	None	None	None	None	None
Michael Proschan	None	None	None	None	None	None
Nina Schooler	None	None	None	None	None	None
Denise Simons-Morton	None	None	None	None	None	None
Janet Wittes	None	None	None	None	None	None

## Course Evaluation Form

We would greatly appreciate your feedback on the course, especially since this is the first time it has been offered. No doubt there will be ample opportunities for improvement! Please complete the Evaluation Form after each lecture and return the completed form at the end of today's symposium. In addition, please complete the Overall Series Evaluation Form after you have attended your last symposium. Please indicate how many symposia you attended.

The Overall Series Evaluation Form is located immediately after this page. The evaluation forms for individual lectures are located behind Tabs I to VI.

Please leave your form(s) at the symposium or mail them to:

Mr. Iain Mackenzie  
The Hill Group  
6701 Democracy Blvd., Suite 515  
Bethesda, MD 20817  
301 897-2789 x124

## Overall Symposium Series Evaluation

I attended the following symposia:

- |                                                                                    |                                                                |
|------------------------------------------------------------------------------------|----------------------------------------------------------------|
| <input type="checkbox"/> IntroductionY                                             | <input type="checkbox"/> Outcome MeasuresY                     |
| <input type="checkbox"/> Design IssuesY                                            | <input type="checkbox"/> Management and Administrative IssuesY |
| <input type="checkbox"/> Sample Characteristics, Y<br>Recruitment, and Maintenance | <input type="checkbox"/> Analytic MethodsY                     |

Scale: 1 = None or not at all      4 = Considerably  
2 = Very little                      5 = Completely  
3 = Moderately                      N/A = Not applicable

### A. Rating of Objectives and Program

1. Please rate the attainment of objectives:

a. Describe the principles underlying the conduct of unbiased clinical trials.

1 2 3 4 5 N/A

b. Contrast biomedical vs. Behavioral interventions in the context of RCTs.

1 2 3 4 5 N/A

c. Evaluate and interpret critically the literature on RCTs for behavioral interventions.

1 2 3 4 5 N/A

d. Contrast and evaluate alternative research designs in terms of their appropriateness.

1 2 3 4 5 N/A

e. Contrast and evaluate methods for monitoring, coordinating, and conducting RCTs.

1 2 3 4 5 N/A

f. Select appropriate outcome measures, enrollment strategies, & randomization techniques.

1 2 3 4 5 N/A

2. The overall quality of the instructional process was an asset to the program.

1 2 3 4 5 N/A      Comments:

3. To what extent did participation in this activity enhance your professional effectiveness?

1 2 3 4 5 N/A      Comments:

4. The overall quality of the conference center facilities was an asset to the program

1 2 3 4 5 N/A      Comments:

## **B. Comments**

*(Use reverse side and additional pages as necessary.)*

1. Are there other topics you would like to have covered in this course or in a related course?

2. Do you have additional comments to improve the quality of this Summer Training Institute?

3. What would you do differently as a result of this course?

4. Has this course changed your future plans for conducting research? If so, how?

## I. Introduction

### Rating of Individual Presentations

Scale: 1 = Poor

2 = Below Average

3 = Average

4 = Above Average

5 = Excellent

N/A = Not applicable

<p><b>Peter Kaufman</b> <b>January 10</b></p>	<p><b>Comments</b> <i>(Use back of page as necessary)</i></p>
<p>Content    1    2    3    4    5    NA</p>	
<p>Audio-visuals    1    2    3    4    5    NA</p>	
<p>Knowledge &amp; Expertise                   1    2    3    4    5    NA</p>	
<p>Teaching Ability                   1    2    3    4    5    NA</p>	
<p><b>Lynda Powell</b> <b>January 10</b></p>	<p><b>Comments</b> <i>(Use back page as necessary)</i></p>
<p>Content    1    2    3    4    5    NA</p>	
<p>Audio-visuals    1    2    3    4    5    NA</p>	
<p>Knowledge &amp; Expertise                   1    2    3    4    5    NA</p>	
<p>Teaching Ability                   1    2    3    4    5    NA</p>	

## II. Design Issues

### *Rating of Individual Presentations*

Scale: 1 = Poor

2 = Below Average

3 = Average

4 = Above Average

5 = Excellent

N/A = Not applicable

<b>Frank Keefe</b> <b>February 13</b>	<b>Comments</b> <i>(Use back of page as necessary)</i>
Content    1    2    3    4    5    NA	
Audio-visuals    1    2    3    4    5    NA	
Knowledge & Expertise 1    2    3    4    5    NA	
Teaching Ability 1    2    3    4    5    NA	
<b>Sheryl Kelsey</b> <b>February 13</b>	<b>Comments</b> <i>(Use back page as necessary)</i>
Content    1    2    3    4    5    NA	
Audio-visuals    1    2    3    4    5    NA	
Knowledge & Expertise 1    2    3    4    5    NA	
Teaching Ability 1    2    3    4    5    NA	
<b>Karina Davidson</b> <b>February 13</b>	<b>Comments</b> <i>(Use back of page as necessary)</i>
Content    1    2    3    4    5    NA	
Audio-visuals    1    2    3    4    5    NA	
Knowledge & Expertise 1    2    3    4    5    NA	
Teaching Ability 1    2    3    4    5    NA	

### III. Sample Characteristics, Recruitment, and Maintenance

#### Rating of Individual Presentations

Scale: 1 = Poor

2 = Below Average

3 = Average

4 = Above Average

5 = Excellent

N/A = Not applicable

<p><b>Janet Wittes</b> <b>March 3</b></p>	<p><b>Comments</b> <i>(Use back of page as necessary)</i></p>
<p>Content    1    2    3    4    5    NA</p>	
<p>Audio-visuals    1    2    3    4    5    NA</p>	
<p>Knowledge &amp; Expertise                   1    2    3    4    5    NA</p>	
<p>Teaching Ability                   1    2    3    4    5    NA</p>	
<p><b>Lynda Powell</b> <b>March 3</b></p>	<p><b>Comments</b> <i>(Use back page as necessary)</i></p>
<p>Content    1    2    3    4    5    NA</p>	
<p>Audio-visuals    1    2    3    4    5    NA</p>	
<p>Knowledge &amp; Expertise                   1    2    3    4    5    NA</p>	
<p>Teaching Ability                   1    2    3    4    5    NA</p>	

## IV. Outcome Measures

### *Rating of Individual Presentations*

Scale: 1 = Poor

2 = Below Average

3 = Average

4 = Above Average

5 = Excellent

N/A = Not applicable

<p><b>Robert Kaplan</b> <b>April 28</b></p>	<p><b>Comments</b> <i>(Use back of page as necessary)</i></p>
<p>Content    1    2    3    4    5    NA</p>	
<p>Audio-visuals    1    2    3    4    5    NA</p>	
<p>Knowledge &amp; Expertise                   1    2    3    4    5    NA</p>	
<p>Teaching Ability                   1    2    3    4    5    NA</p>	
<p><b>Nina Schooler</b> <b>April 28</b></p>	<p><b>Comments</b> <i>(Use back page as necessary)</i></p>
<p>Content    1    2    3    4    5    NA</p>	
<p>Audio-visuals    1    2    3    4    5    NA</p>	
<p>Knowledge &amp; Expertise                   1    2    3    4    5    NA</p>	
<p>Teaching Ability                   1    2    3    4    5    NA</p>	

## V. Management and Administrative Issues

### *Rating of Individual Presentations*

Scale: 1 = Poor

2 = Below Average

3 = Average

4 = Above Average

5 = Excellent

N/A = Not applicable

<p><b>William Harlan</b> <b>May 2</b></p>	<p><b>Comments</b> <i>(Use back of page as necessary)</i></p>
<p>Content    1    2    3    4    5    NA</p>	
<p>Audio-visuals    1    2    3    4    5    NA</p>	
<p>Knowledge &amp; Expertise                   1    2    3    4    5    NA</p>	
<p>Teaching Ability                   1    2    3    4    5    NA</p>	
<p><b>Denise Simons-Morton</b> <b>May 2</b></p>	<p><b>Comments</b> <i>(Use back page as necessary)</i></p>
<p>Content    1    2    3    4    5    NA</p>	
<p>Audio-visuals    1    2    3    4    5    NA</p>	
<p>Knowledge &amp; Expertise                   1    2    3    4    5    NA</p>	
<p>Teaching Ability                   1    2    3    4    5    NA</p>	

## VI. Analytic Methods

### *Rating of Individual Presentations*

Scale: 1 = Poor

2 = Below Average

3 = Average

4 = Above Average

5 = Excellent

N/A = Not applicable

<p><b>Janet Wittes</b> <b>June 6</b></p>	<p><b>Comments</b> <i>(Use back of page as necessary)</i></p>
<p>Content    1    2    3    4    5    NA</p>	
<p>Audio-visuals    1    2    3    4    5    NA</p>	
<p>Knowledge &amp; Expertise                   1    2    3    4    5    NA</p>	
<p>Teaching Ability                   1    2    3    4    5    NA</p>	
<p><b>Michael Proschan</b> <b>June 6</b></p>	<p><b>Comments</b> <i>(Use back page as necessary)</i></p>
<p>Content    1    2    3    4    5    NA</p>	
<p>Audio-visuals    1    2    3    4    5    NA</p>	
<p>Knowledge &amp; Expertise                   1    2    3    4    5    NA</p>	
<p>Teaching Ability                   1    2    3    4    5    NA</p>	