Summer Training Institute for Randomized Clinical Trials
Involving Behavioral Interventions

Tab 2
Daily Schedules and Study Groups

Overview

Tabs A – L provide the schedules for the lectures and Study Groups. Besides listing the theme for the day and the lectures, we are providing reprints of required readings for each lecture. In some instances, we are also suggesting additional readings for future reference. (See Tab 6 for a complete bibliography. Reprints of *Required Readings* are provided at Tab 2, immediately following the associated lecture schedule. Reprints of some *suggested reading* are provided at Tab 6 in alphabetical order by author.)

Lecture Evaluations

Please complete and hand in the Evaluation Forms for the daily lectures either immediately following the lecture or at the end of the day. You will find the forms in this Resource Binder for each day's schedule at Tab 2, A-L.

At the end of the course, please complete the Overall Course Evaluation Form, which you can find at Tab 1. (See the Table of Contents for Tab 1).

Tab	Date	Theme
A	July 29 Sunday Evening	Welcome and Orientation
B	July 30 Monday	History and Methods of RCTs
C	July 31 Tuesday	Research Designs
D	August 1 Wednesday	Designing RCTs
E	August 2 Thursday	Research Ethics
F	August 3 Friday	Defining and Selecting Participants
August 4 – 5 (Saturday and Sunday): Recreation		
G	August 5 Sunday Evening	Getting a Research Grant from the NIH
H	August 6 Monday	Psychological Assessment, Fidelity, and Adherence
I	August 7 Tuesday	Quality Control
J	August 8 Wednesday	Multi-center RCTs
K	August 9 Thursday	Presentations by Study Groups
L	August 10 Friday	Presentations by Study Groups Graduation and Farewell

Study Groups

For most afternoons we will divide into five Study Groups to discuss the daily themes, lectures, and readings as well as to eventually design RCTs! Please note to which Study Group you have been assigned. During the first week of the course, the Study Groups will discuss issues and work on assignments associated with the daily lectures. During the second week, each Study Group will be assigned a topic on which to design a RCT. The Study Groups will present their designs for discussion and friendly critique on August 9th and 10th.

Group 1
West Room

Paul Arnstein
Janet C' de Baca
Caroyln Furr-Holden
Mollie W. Howerton
Yoriko Kozuki
Claudia Zayfert

Faculty: Beryl Koblin (Week 1) and Genell Knatterrud (Week 2)

Group 2
Board Room

Audie Atienza
Catherine A. Carr
Ricky Greenwald
Karen Ingersoll
Steven C. Palmer
Kenneth P. Tercyak

Faculty: Leonard Epstein (Week 1) and Peter Kaufmann (Week 2)

Group 3
East Room

Stephanie Berns
Michele Cooley-Quille
Gregory L. Greenwood
Linda Patrick-Miller
Justin M. Nash
Cynthia Turk

Faculty: Robert Kaplan (Week 1) and Nancy Miller (Week 2)

Group 4
Studio Room

Barbara Shelton Broome
David W. Coon
Michelle Y. Martin
Brian E. Saelens
Joseph B. Stanfor
Mildred Vera

Faculty: Frank Keefe (Week 1) and
Nina Schooler (Week 2)

Group 5
Studio Room

Todd C. Buckley
Diane Downs
Stacey Hart
Cynthia Myers
Anna Napoles Springer
Carolyn B. Yucha

Faculty: Lynda Powell (Week 1) and Sherry Willis (Week 2)

Tab A
Sunday, July 29, 2001

Introduction to the Summer Institute

1:00 PM	Arrival and registration	Lobby
6:00 – 7:30 PM	Dinner	Main dinning room
7:30 – 9:00 PM	Welcome and Orientation Introduction, Goals, and Issues Recommended Reading: Textbook, Chapter 1	**East Room** Ronald Abeles and Peter Kaufmann

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Tab A
Sunday, July 29, 2001

Introduction to the Summer Institute

Please rate tonight's presentation using the following scale and give us your comments. Only cumulative (i.e., non-identifiable) information will be provided to the faculty. Your input will be used to improve future offerings of this Summer Training Institute

Rating of Individual Presentations

Scale: 1 = Poor 2 = Below Average 3 = Average	4 = Above Average 5 = Excellent NA= Not applicable
Introduction, Goals, and Issues **Peter Kaufmann**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	

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Tab B
Monday, July 30, 2001

History and Methods of Randomized Clinical Trials

7:30 – 8:30 AM	Breakfast	
8:30 – 9:00 AM **East Room**	Administrative and logistical announcements (if any)	Ron Abeles and Peter Kaufman
9:00 – 10:00 AM	**History, Philosophy, and the Basic Principles of Randomized Clinical Trials** Assigned Readings: • Infant Health and Development Program, Enhancing the outcomes of low-birth-weight, premature infants, *JAMA*, June 13, 1990, 263 (22), 3035-3042. • The MTA Cooperative Group, A 14-month randomized clinical trial of treatment strategies for Attention-Deficit/Hyperactivity Disorder, *Arch Gen Psychiatry*, 56, Dec 1999, 1073-1086. • The MTA Cooperative Group, Moderators and mediators of treatment response for children with Attention-Deficit/Hyperactivity Disorder, *Arch Gen Psychiatry*, 56, Dec 1999, 1088-1096. Suggested Readings: • Textbook Chapters 2-7 (Note some of these chapters are assigned for subsequent lectures.)	Helena Kraemer
10:00 – 10:30 AM	Refreshment Break	
10:30 – 11:30 AM	**Statistical Hypothesis Testing** Assigned Readings: • Begg C, *et al.,* Improving the quality of reporting of randomized controlled trials: The CONSORT statement. *JAMA,* 1999, *276,* 637-639.	Helena Kraemer
11:30 AM – 12:00 PM	Discussion and Questions	Helena Kraemer
12:00 – 1:30 PM	Lunch	

1:30 – 3:30 PM	**Study Groups** 1. Using either IHDP study or the MTA study, what strategies did the groups use to satisfy the "rules" of doing RCTs? 2. What alternative strategies do you think might have been considered, without changing the research question? Would you have chosen a different strategy? Why? Why do you think the Research Steering Committees of these studies chose otherwise? 3. Go over the CONSORT statement. In what ways does this policy enforce the "rules" of the RCT? What other requirements are added and why?	Group 1: West Room Group 2: Board Room Group 3: East Room Group 4: Studio Room Group 5: Studio Room
3:30 – 4:00 PM	Refreshment Break	

4:00 – 5:00 PM **East Room**	**A Selected History of Behavioral Clinical Trials: What Went Wrong?** Assigned Readings: • Textbook: pp. 20, 46-47; 82-85 • Frasure-Smith N & Prince R, Long-term follow-up of the Ischemic Heart Disease Life Stress Monitoring Program, *Psychosom Med,* 1989, *51,* 485-513. • Powell LH, Unanswered questions in the Ischemic Heart Disease Life Stress Monitoring Program, *Psychosm Med,* 1989, *51,* 479-484. Suggested Readings: • Jones DA & West RR. Psychological rehabilitation after myocardial infarction: Multicentre randomised controlled trial. *BMJ* 1996; *313*: 1517-1521. • Blumenthal JA, Jiang W, Babyak MA, Krantz DS et al. Stress management and exercise training in cardiac patients with myocardial ischemia. Effects on prognosis and evaluation of mechanisms. *Arch Intern Med* 1997;*157*:2213-2223. • Frasure-Smith N, Lesperance F, Prince RH, Verrier P et al. Randomised trial of home-based psychosocial nursing intervention for patients recovering from myocardial infarction. *Lancet* 1997; *350*: 473-479. Also Commentary p. 457.	Lynda Powell
6:00 – 7:30 PM	Dinner	
7:30 – 8:30 PM **East Room**	Discussion: Critique the following behavioral trailing, drawing on the concepts provided thus far: Harris, WS, *et al.,* A randomized controlled trial of the effects of remote, intercessory prayer on outcomes in patients admitted to the coronary care unit, *Arch Intern Med,* 1999, *159:* 2273-2278	Moderator: Lynda Powell

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Tab B
Monday, July 30, 2001

History and Methods of Randomized Clinical Trials

Please rate each presentation using the following scale and give us your comments. Only cumulative (i.e., non-identifiable) information will be provided to the faculty. Your input will be used to improve future offerings of this Summer Training Institute

Rating of Individual Presentations

Scale: 1 = Poor 2 = Below Average 3 = Average	4 = Above Average 5 = Excellent NA= Not applicable
History, Philosophy, and the Basic Principles of Randomized Clinical Trials **Helena Kraemer**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	
Statistical Hypothesis Testing, **Helena Kraemer**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	
A Selected History of Behavioral Clinical Trials: What Went Wrong? **Lynda Powell**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	

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Tab C
Tuesday, July 31, 2001

Research Design

7:30 – 8:30 AM	Breakfast	
8:30 – 9:00 AM **East Room**	Administrative and logistical announcements (if any)	Ron Abeles and Peter Kaufman
9:00 – 10:00 AM	**Introduction and Overview** **Testing Treatment Efficacy** Assigned Readings (For all three lectures): • Textbook Ch 4 • Ader R and Cohen N, Behavioralllly condititioned immunosuppression and murine systemic lupus erthermatosus, *Science,* 1982, *215,* 1534-6 • Hrobjartsson A and Gotzsche PC, Is the placebo powerless? An analysis of clinical trials comparing placebo with no treatment, *NEJM,* 2001, *344:* 1594-602 • Turner JA, *et al.,* The importance of placebo effects in pain treatment and research, *JAMA,* 1994, *271:* 1609-14 Suggested Readings: • Beecher, HK, The powerful placebo, *JAMA,* 1955, *27:* 1602-6 • Keefe, FJ, *et al.,* Pain coping skills training in the management of osteoarthritic knee pain: A comparative study. *Behavior Therapy,* 1990, *21:* 49-62.	Leonard Epstein Frank Keefe
10:00 – 10:30 AM	Refreshment Break	
10:30 – 11:30 AM	**Testing Treatment Effectiveness**	Robert Kaplan
11:30 AM – 12:00 PM	Discussion and Questions	Discussion Leaders Epstein, Kaplan, and Keefe
12:00 – 1:30 PM	Lunch	

1:30 – 3:30 PM	**Study Groups** Relevance of research on effects of placebos on need for controlling for behavioral placebo effects in clinical trials	Group 1: West Room Group 2: Board Room Group 3: East Room Group 4: Studio Room Group 5: Studio Room
3:30 – 4:00 PM	Refreshment Break	
4:00 – 5:00 PM **East Room**	**Behavioral Placebo**	Robert Kaplan and Frank Keefe
6:00 – 7:30 PM	Dinner	

Tab C
Tuesday, July 31, 2001

Research Design

Please rate each presentation using the following scale and give us your comments. Only cumulative (i.e., non-identifiable) information will be provided to the faculty. Your input will be used to improve future offerings of this Summer Training Institute

Rating of Individual Presentations

Scale: 1 = Poor 2 = Below Average 3 = Average	4 = Above Average 5 = Excellent NA= Not applicable
Introduction and Overview **Leonard Epstein**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	
Testing Treatment Efficacy **Frank Keefe**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	
Testing Treatment Effectiveness **Robert Kaplan**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	

Scale: 1 = Poor 2 = Below Average 3 = Average	4 = Above Average 5 = Excellent NA= Not applicable
Behavioral Placebo **Robert Kaplan and Frank Keefe**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	

Tab D
Wednesday, August 1, 2001

Designing Randomized Clinical Trials

7:30 – 8:30 AM	Breakfast	
8:30 – 9:00 AM **East Room**	Administrative and logistical announcements (if any)	Ron Abeles and Peter Kaufman
9:00 – 10:00 AM	**Trial Designs** Assigned Readings: • Textbook, Ch. 4 Suggested Readings: • Pocock, S. *Clinical Trials*, chapter 8, pages 110-122, Wiley, New York, 1984.	Michael Proschan
10:00 – 10:30 AM	Refreshment Break	
10:30 – 11:30 AM	**Randomization and Selection of Endpoints** Assigned Readings: • Textbook, Ch. 2 and 5 • The Cardiac Arrhythmia Suppression Trial (CAST) Investigators, Preliminary report : Effect of encainide and flecainide on mortality in a randomized trial of arrhythmia suppression after myocardial infarction, *N Engl J Med*, 1989, *321*: 406-412 • Coronary Drug Project Research Group, Influence of adherence to treatment and response of cholesterol on mortality in the Coronary Drug Project, *N Engl J Med*, 1980, *303*: 1038-1041	Sheryl Kelsey
11:30 AM – 12:00 PM	Discussion and Questions	Michael Proschan and Sheryl Kelsey
12:00 – 1:30 PM	Lunch	

1:30 – 3:30 PM	**Study Groups** Topic: Blinding • Textbook, Ch 6 • Rosa, Linda, *et al.,* A close look at therapeutic touch. *JAMA*, April 1, 1998, *279*(13), pp. 1005-1010 • Letters to the Editor, *JAMA*, December 9, 1998, *280* (22), 1905-1908	Group 1: West Room Group 2: Board Room Group 3: East Room Group 4: Studio Room Group 5: Studio Room
3:30 – 4:00 PM	Refreshment Break	
4:00 – 5:00 PM **East Room**	**Analysis and Sample Size/Power** Assigned Readings: • Textbook, Ch. 7	Michael Proschan
6:00 – 7:30 PM	Dinner	

Tab D
Wednesday, August 1, 2001

Designing Randomized Clinical Trials

Please rate each presentation using the following scale and give us your comments. Only cumulative (i.e., non-identifiable) information will be provided to the faculty. Your input will be used to improve future offerings of this Summer Training Institute

Rating of Individual Presentations

Scale: 1 = Poor 2 = Below Average 3 = Average	4 = Above Average 5 = Excellent NA= Not applicable
Trial Designs **Michael Proschan**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	
Randomization and Selection of Endpoints **Sheryl Kelsey**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	
Analysis and Sample Size/Power **Michael Proschan**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	

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Tab E
Thursday, August 2, 2001

Research Ethics

7:30 – 8:30 AM	Breakfast	
8:30 – 9:00 AM **East Room**	Administrative and logistical announcements (if any)	Ron Abeles and Peter Kaufman
9:00 – 10:00 AM	**Basic Ethical Standards** Assigned Readings: • The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research, April 18, 1979 (Department of Health, Education, and Welfare) • Code of Federal Regulations, Title 45, Part 46, Subpart A, Projection of Human Subjects. • Helsinki Declaration: Ethical Principles for Medical Research Involving Human Subjects (World Medical Association), revised October 2000.	Baruch Brody
10:00 – 10:30 AM	Refreshment Break	
10:30 – 11:30 AM	**Special Ethical Issues Related to Randomized Controlled Trials** Assigned Readings: • Brody, B. A., The Ethics of Biomedical Research: An International Perspective. New York: Oxford University Press, 1998, pp. 72-75 & Chapter 7. • Code of Federal Regulations, Title 21, Section 314.126, Adequate and Well-controlled Studies.	Baruch Brody
11:30 AM – 12:00 PM	Discussion and Questions	Baruch Brody
12:00 – 1:30 PM	Lunch	

1:30 – 3:30 PM	**Study Groups** • How do the basic protections for human subjects deal with, or fail to deal with, the ethical issues raised by clinical trials? • Do clinical trials involving behavioral interventions raise different ethical questions than other clinical trials? • Does the resolution of the ethical issues common to all clinical trials differ when the trials involve behavioral interventions? • Are there special ethical issues related to choice of study population when a clinical trial involves behavioral interventions?	Group 1: West Room Group 2: Board Room Group 3: East Room Group 4: Studio Room Group 5: Studio Room
3:30 – 4:00 PM	Refreshment Break	
4:00 – 5:00 PM **East Room**	**From Protection to Inclusion** Assigned Readings: • National Institutes of Health Policy and Guidelines for the Inclusion of Children as Participants in Research Involving Human Subjects, March 6, 1998. • National Institutes of Health Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, March 18, 1994.	Baruch Brody
6:00 – 7:30 PM	Dinner	

Tab E
Thursday, August 2, 2001

Research Ethics

Please rate each presentation using the following scale and give us your comments. Only cumulative (i.e., non-identifiable) information will be provided to the faculty. Your input will be used to improve future offerings of this Summer Training Institute

Rating of Individual Presentations

Scale: 1 = Poor 2 = Below Average 3 = Average	4 = Above Average 5 = Excellent NA= Not applicable
Basic Ethical Standards **Baruch Brody**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	
Special Ethical Issues Related to RCTs **Baruch Brody**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	
From Protection to Inclusion **Baruch Brody**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	

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Tab F
Friday, August 3, 2001

Defining and Selecting Participants

7:30 – 8:30 AM	Breakfast	
8:30 – 9:00 AM **East Room**	Administrative and logistical announcements (if any)	Ron Abeles and Peter Kaufman
9:00 – 10:00 AM	**Recruitment and Retention** Assigned Readings: • Textbook, Ch. 9	Lynda Powell
10:00 – 10:30 AM	Refreshment Break	
10:30 – 11:30 AM	**Adherence in Trials** Assigned Readings: • Martin KA, *et al.,* Who will adhere? Key issues in the study and prediction of adherence in randomized controlled trials, *Controlled Trials,* 2000, *21*, 195S-199S • Shumaker, SA, *et al.,* Enhancing adherence in randomized controlled trials, *Controlled Trials,* 2000, *21*, 226S-232S • Sieber WJ and Kaplan RM, Informed adherence: The need for shared medical decision making, *Controlled Trials,* 2000, *21*, 233S-240S Suggested Readings: • Textbook Ch. 13	Robert Kaplan
11:30 AM – 12:00 PM	Discussion and Questions	Discussion Leaders Robert Kaplan and Lynda Powell
12:00 – 1:30 PM	Lunch	

1:30 – 3:30 PM	**Study Groups** • Design a recruitment plan for a study on the long term effects of dietary fat restriction. The the plan must consider subject incentives, medical screening, ethnic diversity, and community representativeness.	Group 1: West Room Group 2: Board Room Group 3: East Room Group 4: Studio Room Group 5: Studio Room
3:30 – 4:00 PM	Refreshment Break	
4:00 – 5:00 PM **East Room**	**Ethics and Study Participation**	Robert Kaplan
6:00 – 7:30 PM	Dinner	

Tab F
Friday, August 3, 2001

Defining and Selecting Participants

Please rate each presentation using the following scale and give us your comments. Only cumulative (i.e., non-identifiable) information will be provided to the faculty. Your input will be used to improve future offerings of this Summer Training Institute

Rating of Individual Presentations

Scale: 1 = Poor 2 = Below Average 3 = Average	4 = Above Average 5 = Excellent NA= Not applicable
Recruitment and Retention **Lynda Powell**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	
Adherence in Trials **Robert Kaplan**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	
Ethics and Study Participation **Robert Kaplan**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	

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Tab G
Saturday and Sunday, August 4-5, 2001

7:30 – 8:30 AM	Breakfast	
8:30 – 10:30 AM	Recreation*	On your own
10:00 – 10:30 AM	Refreshment Break	
10:30 AM – 12:00 PM	Recreation*	On your own
12:00 – 1:30 PM	Lunch (box lunches available)	
12:00 – 3:30 PM	Recreation*	On your own
3:30 – 4:00 PM	Refreshment Break	
4:00 – 6:00 PM	Recreation*	On your own
6:00 – 7:30 PM	Dinner	
August 5 ***Sunday Only*** 7:30 – 8:30 PM **East Room**	Getting a Research Grant from the NIH	Ronald Abeles

*See Tab 5 for Weekend Recreation Options

Tab G
Saturday and Sunday, August 4-5, 2001

Please rate each presentation using the following scale and give us your comments. Only cumulative (i.e., non-identifiable) information will be provided to the faculty. Your input will be used to improve future offerings of this Summer Training Institute

Rating of Individual Presentations

Scale: 1 = Poor 2 = Below Average 3 = Average	4 = Above Average 5 = Excellent NA= Not applicable
Applying for NIH Research Grants **Ronald Abeles**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	

Tab H
Monday, August 6, 2001

Psychosocial Assessment, Fidelity, and Adherence

7:30 – 8:30 AM	Breakfast	
8:30 – 9:00 AM **East Room**	Administrative and logistical announcements (if any)	Ron Abeles and Peter Kaufman
9:00 – 10:00 AM	**Linking Hypotheses, Outcomes, and Assessment Measures**	Nina Schooler
10:00 – 10:30 AM	Refreshment Break	
10:30 – 11:30 AM	**Fidelity** Assigned Readings: • Textbook Ch 10 Suggested Readings: • *To be assigned*	Sherry Willis and Nancy Miller
11:30 AM – 12:00 PM	Discussion and Questions	Discussion Leaders Nancy Miller, Nina Schooler, and Sherry Willis
12:00 – 1:30 PM	Lunch	
1:30 – 3:30 PM	**Study Groups** Design of RCT on assigned topic.	Group 1: West Room Group 2: Board Room Group 3: East Room Group 4: Studio Room Group 5: Studio Room
3:30 – 4:00 PM	Refreshment Break	
4:00 – 5:00 PM **East Room**	**Adherence** Assigned Readings: • Textbook Ch. 13 Suggested Readings: • *To be assigned*	Nancy Miller and Sherry Willis
6:00 – 7:30 PM	Dinner	

Tab H
Monday, August 6, 2001

Psychosocial Assessment, Fidelity, and Adherence

Please rate each presentation using the following scale and give us your comments. Only cumulative (i.e., non-identifiable) information will be provided to the faculty. Your input will be used to improve future offerings of this Summer Training Institute

Rating of Individual Presentations

Scale: 1 = Poor 2 = Below Average 3 = Average	4 = Above Average 5 = Excellent NA= Not applicable
Linking Hypotheses, Outcomes, and Assessment Measures **Nina Schooler**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	
Fidelity **Sherry Willis and Nancy Miller**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	
Adherence **Nancy Miller and Sherry Willis**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	

Tab I
Tuesday, August 7, 2001

Quality Assurance

7:30 – 8:30 AM	Breakfast	
8:30 – 9:00 AM **East Room**	Administrative and logistical announcements (if any)	Ron Abeles and Peter Kaufman
9:00 – 10:00 AM	**Overview** Assigned Readings: • Textbook, Ch. 10, Data Collection and Quality Control • Knatterud GL, Rockhold FW, George SL, *et al*. Guidelines for quality assurance in multicenter trials: a position paper. *Controlled Clin Trials* 1998; *19:*477-493. • Meinert CL. *Clinical Trials: Design, Conduct and Analysis*. Chapter 16 Quality Assurance. New York, New York: Oxford University Press, 1986, pages 166-176	Genell Knatterud
10:00 – 10:30 AM	Refreshment Break	
10:30 – 11:30 AM	**Prevention of Problems** Assigned Reading • Textbook, Ch. 13, Participant Adherence • Buyse M, George SL, Evans S*, et al*. The role of biostatistics in the prevention, detection and treatment of fraud in clinical trials*. Stat Med* 1999; *18:* 3435-3451..	Genell Knatterud
11:30 AM – 12:00 PM	Discussion and Questions	Genell Knatterud
12:00 – 1:30 PM	Lunch	

1:30 – 3:30 PM	**Study Groups** Design of RCT on assigned topic	Group 1: West Room Group 2: Board Room Group 3: East Room Group 4: Studio Room Group 5: Studio Room
3:30 – 4:00 PM	Refreshment Break	
4:00 – 5:00 PM **East Room**	**Monitoring Clinical Sites**	Genell Knatterud
6:00 – 7:30 PM	Dinner	

Tab I
Tuesday, August 7, 2001

Quality Assurance

Please rate each presentation using the following scale and give us your comments. Only cumulative (i.e., non-identifiable) information will be provided to the faculty. Your input will be used to improve future offerings of this Summer Training Institute

Rating of Individual Presentations

Scale: 1 = Poor 2 = Below Average 3 = Average	4 = Above Average 5 = Excellent NA= Not applicable
Overview **Genell Knatterud**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	
Prevention of Problems **Genell Knatterud**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	
Monitoring of Clinical Sites **Genell Knatterud**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	

Tab J
Wednesday, August 8, 2001

Multi-centered Randomized Clinical Trials

7:30 – 8:30 AM	Breakfast	
8:30 – 9:00 AM **East Room**	Administrative and logistical announcements (if any)	Ron Abeles and Peter Kaufman
9:00 – 10:00 AM	**When the Outcome Is Not Immediate: Time to Event - Longitudinal (Repeated) Measurements** Assigned Readings: • Textbook, Chapter 12 (pp. 198-199), Chapter 14 • Hallstrom, AP, Sullivan, SD. On estimating costs for economic evaluation in failure time studies. *Medical Care*, 1998, *36*(3), 433-436 Suggested Readings: • Diggle, PJ, Liang, KY, Zeger, SL. Chapter 1. *Analysis of Longitudinal Data*. Oxford Science Publications. 1998; Ch. 1, pp. 1-22 • Ghosh, D., Methods for Analysis of Multiple Events in the Presence of Death. *Control Clin Trials*, 2000;*21*:115-126	Alfred Hallstrom
10:00 – 10:30 AM	Refreshment Break	
10:30 – 11:30 AM	**DSMBs and Sequential Monitoring** Assigned Readings: • Textbook Chapter 15 Suggested Readings: • DeMets, DL. Data monitoring and sequential analysis-An academic perspective *J Acquir Immune Defic Syndr* 1990;3 (Supplement):S124-33. • Task Force of the Working Group on Arrhythmias of the European Society of Cardiology, The early termination of clinical trials: Causes, consequences, and control *Circulation* 1994;89 (6):2892-907.	Alfred Hallstrom

	• Whitehead, J. On the bias of maximum likelihood estimation following a sequential test *Biometrika*, 1986;73, 3:573-81. • Fisher, LD. Self-Designing Clinical Trials *Stat Med* 1998;17:1551-62. • Califf, RM, Lee, KL. Data and safety monitoring committees: Philosophy and practice *Am Heart J* 2001;141:154-5. • Cairns, JA, Hallstrom, A, Held, P. Should all trials have a Data Safety and Monitoring Committee? *Am Heart J* 2001;141:156-63. • Pocock, S, Furberg, CD. Procedures of Data and Safety Monitoring Committees. *Am Heart J* 2001;141:289-94. • Weaver, DW, Greenberg, S. Making changes in clinical trials. *Am Heart J* 2001;141:295-300 • Califf, RM, Ellenberg, SS. Statistical approaches and policies for the operations of Data and Safety Monitoring Committees. *Am Heart J* 2000;141:301-5. • Fisher, L, Klibaner, M. Regulatory issues for Data and Safety Monitoring Committees. *Am Heart J* 2001;141:536-41. • Packer, M, Wittes, J. Stump, D. Terms of reference for Data and Safety Monitoring Committees. *Am Heart J* 2001;141:542-7 • DeMets DL, Yusuf, S. The Data and Safety Monitoring Committee: Some final thoughts. *Am Heart J* 2001;141:548-9 • Pocock, SJ. When to stop a clinical trial. Education and Debate.	
11:30 AM – 12:00 PM	Discussion and Questions	Alfred Hallstrom
12:00 – 1:30 PM	Lunch	

1:30 – 3:30 PM	**Study Groups** Design of RCT on assigned topic	Group 1: West Room Group 2: Board Room Group 3: East Room Group 4: Studio Room Group 5: Studio Room 5
3:30 – 4:00 PM	Refreshment Break	
4:00 – 5:00 PM **East Room**	**Multi-center Trials, Multi-trials, Meta-analysis, and Mega-analysis** Assigned Readings: • Text Chapter 17 (pp. 308-16), Chapters 18, 19 • Cappelleri, JC, et al. Large trials vs. meta-analysis of smaller trials: How do the results compare? *JAMA* 1996, Oct 23/30; 276, (16):1332-38. • Domanski, MJ, Friedman, LM. Relative role of meta-analysis and randomized controlled trials in the assessment of medical therapies. *Am J Cardiol* 1994; 74:395-6. • Geller, NL, Proschan, M. Meta-analysis of clinical trials: A consumer's guide *J Biopharm Stat* 1996;6 (4):377-94. • Sterling, TD, et al. Publication decisions revisited: The effect of the outcome of statistical tests on the decision to publish and vice versa. *The American Statistician* 1995;49 (1):108-12. • Working Group on Recommendations for Reporting of Clinical Trials in the Biomedical Literature, Call for comments on a proposal to improve reporting of clinical trials in the biomedical literature, *Ann Intern Med* 1994; 121 (11):894-5. Suggested Readings: • DerSimionian, R. Meta-analysis in the design and monitoring of clinical trials. *Stat Med* 1996; 15:1237-48. • Discussion. *Stat Med* 1996; 15: 1259-62, 1281-83, 1307-11.	Alfred Hallstrom

6:00 – 7:30 PM	Dinner

Tab J
Wednesday, August 8, 2001

Multi-centered Randomized Clinical Trials

Please rate each presentation using the following scale and give us your comments. Only cumulative (i.e., non-identifiable) information will be provided to the faculty. Your input will be used to improve future offerings of this Summer Training Institute

Rating of Individual Presentations

Scale: 1 = Poor 2 = Below Average 3 = Average	4 = Above Average 5 = Excellent NA= Not applicable
When the Outcome Is Not Immediate **Alfred Hallstrom**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	
DSMBs and Sequential Monitoring **Alfred Hallstrom**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	
Multi-center Trials, Multi-trials, Meta- and Mega-analysis **Alfred Hallstrom**	Comments (Use back of page as necessary)
Content 1 2 3 4 5 NA	
Audio-visuals 1 2 3 4 5 NA	
Knowledge and expertise 1 2 3 4 5 NA	
Teaching ability 1 2 3 4 5 NA	

Tab K
Thursday, August 9, 2001

Study Group Presentations

7:30 – 8:30 AM	Breakfast	
8:30 – 9:00 AM **East Room**	Administrative and logistical announcements (if any)	Ron Abeles and Peter Kaufman
9:00 – 10:00 AM **East Room**	Study Group Presentation	Group 1
10:00 – 10:30 AM	Refreshment Break	
10:30 – 11:30 AM	Discussion	Genell Knatterud, Moderator
11:30 – 1:00 PM	Lunch	
1:00 – 2:00 PM **East Room**	Study Group Presentation	Group 2
2:00 – 3:00 PM	Discussion	Peter Kaufmann, Moderator
3:00 – 3:30 PM	Refreshment Break	
3:30 – 4:30 PM	Study Group Presentation	Group 3
4:30 – 5:30 PM	Discussion	Nancy Miller, Moderator
6:00 – 7:30 PM	Dinner	

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Tab L
Friday, August 10, 2001

Study Group Presentations and Graduation

7:30 – 8:30 AM	Breakfast	
8:30 – 9:00 AM **East Room**	Administrative and logistical announcements (if any)	Ron Abeles and Peter Kaufman
9:00 – 10:00 AM **East Room**	Study Group Presentation	Group 4
10:00 – 10:30 AM	Refreshment Break	
10:30 – 11:30 AM	Discussion	Nina Schooler, Moderator
11:30 AM – 1:00 PM	Lunch	
1:00 – 2:00 PM **East Room**	Study Group Presentation	Group 5
2:00 – 3:00 PM	Discussion	Sherry Willis, Moderator
3:00 – 3:30 PM	Refreshment Break	
3:30 – 4:30 PM **East Room**	Graduation	Ronald Abeles and Peter Kaufmann
4:30 PM	Adjournment and departure	