

Summer Training Institute for Randomized Clinical Trials Involving Behavioral Interventions

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Training Goals

Welcome to the Summer Training Institute for Randomized Clinical Trials involving Behavioral Interventions organized by the Office of Behavioral and Social Sciences Research (OBSSR), Office of the Director, National Institutes of Health (NIH). Over the ten days of the course, you will gain a thorough grounding in the conduct of randomized clinical trials and develop competence in the planning, design, and execution of clinical trials involving behavioral interventions. We have designed the course so that you will be able to:

- ✓ Describe the principles underlying the conduct of unbiased clinical trials.
- ✓ Contrast biomedical *vs.* behavioral interventions in the context of Randomized Clinical Trials (RCTs).
- ✓ 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
- ✓ Design a specific research proposal in collaboration with a multidisciplinary team.

Towards these ends, we have organized most days around morning lectures and afternoon study groups, with ample time throughout the day and evening for informal conversations, “networking,” and recreation. We hope that the result will be an enriching and enjoyable learning environment for both the student participants and the faculty.

Resource Binder

This *Resource Binder* includes both logistical information about how we have organized the course and instructional materials. The *Resource Binder* is your guide to course and its daily activities. Please read it carefully in advance of your arrival at the Summer Training Institute. While we have tried to distribute all of the necessary information and materials in advance of your arrival at the Summer Training Institute, we know there will be last minute additions. We will provide these to you at the appropriate time during the course.

Administrators: Whom to contact for what

Before, during, and after the Summer Training Institute, you will no doubt have questions. Please do not hesitate to contact us as follows.

Course Content: Organization, Lectures, Study Groups, Readings, Assignments

Ronald P. Abeles, Ph.D.
OBSSR
Gateway Building, Room 2C234
Bethesda, MD 20892-9205
Phone: 301-496-7859 Fax: 301-435-8779
E-mail: abeles@nih.gov

Peter Kaufman, Ph.D.
National Heart, Lung, and Blood Institute
II Rockledge Center, Room 8118
6701 Rockledge Drive MSC 7936
Bethesda, MD 20892-7936
Phone: 301-435-0404 Fax: 301-480-1773
E-mail: kaufmanp@nih.gov

Logistics: Travel, Housing, Continuing Professional Education Credit, Reimbursement

Ms. Gale Quilter
TASCON
1803 Research Blvd, Suite 305
Rockville, MD 20850
Phone: 301-315-9000 ext. 268 Fax: 301-738-9783
E-mail: gquilter@tascon.com

TASCON staff will be available on July 29th and August 10th to provide assistance in arriving and departing. During the course, **Ms. Diane Downs**, RN (Rush-Presbyterian-St. Luke's Medical Center) will be providing assistance to us in running the course while also participating in the lectures and study groups.

Booking Transportation

Please make all of your arrangements for travel through our travel agency, American Voyages. We have made arrangements with American Voyages to provide you with a prepaid plane or train ticket for the lowest available, direct, roundtrip fare. To make your reservation, please contact the travel agency at **1-800-322-3377** between 8:30 a.m. and 6:00 p.m. Eastern Time, and reference the meeting code, **3059-016**. American Voyages will work with you to ensure that you receive the most economical fare. **Please contact them as soon as possible to take advantage of advance purchase pricing.**

Once you have made a reservation, American Voyages will mail your ticket or arrange for electronic ticketing. If you do not receive your ticket, please call Gale Quilter immediately at TASCON at (301) 315-9000, ext. 268.

American Voyages will provide you with a nonrefundable ticket. If you do not attend the meeting after being ticketed, you will be expected to reimburse TASCON for the cost of the ticket within 30 days of the meeting.

If you intend to drive to the meeting, you will be reimbursed at the rate of **\$0.345/mile**, plus any tolls, for the use of your private auto. Reimbursement of long distance travel by private automobile cannot exceed the amount to be paid for air or rail travel by the most

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direct route at the lowest reasonable fare. It is necessary to keep odometer readings and obtain receipts for parking and tolls. Car rental is not a reimbursable cost without prior written approval.

Transportation to/from Airports and Airlie

Airlie suggests either of these two van services, Fauquier Taxicab Service (888) 557-2577 or Elite Chauffeur Service (540) 349-2333. From Ronald Reagan Washington National Airport the fare is approximately \$75.00 + tip and from Dulles International Airport it would be approximately \$60.00 + tip. **Note:** Receipts are necessary only for any one cost that exceeds \$75, including taxi fares and airport parking.

Dress Code

Casual attire is all that you need for the course. The weather forecast for August is “hot and humid with afternoon thunderstorms.” You should bring light, comfortable clothing such as short-sleeve shirts/blouses, walking shorts, and sun hat as well as a rain jacket or umbrella. Don’t forget a swim suit for enjoying the pool! If you plan on hiking, for example in the Shenandoah National Park, you will need sturdy walking shoes/boots, a hat, water bottle, and a small backpack for your box lunch. For the air-conditioned meeting rooms and Luray Caverns (underground temperature around 60) you may want a sweater and long pants. Are you allergic to mosquitoes? Since they will be coming for dinner (you!), you should also bring insect repellent and anti-itch cream!

Airlie Conference Center

The course will be held at the Airlie Conference Center (www.airlie.com) in the foothills of the Appalachian Mountains in Northern Virginia, “providing a serene atmosphere for work and thought in a community of scholars.” Airlie, VA is approximately 60 minutes driving time from Washington, DC. The closest airport is Dulles International (IAD), which is about 45 minutes away by car. National Airport (DCA) is about 60 minutes driving time. All housing, meals, lectures, and study groups will take place at the Airlie Conference Center. Check-in time is 2:00 PM and check-out time is 11:30 AM.

Address

6809 Airlie Road
Warrenton, Virginia 20187

Phone Numbers

Phone: 540-347-1300
Fax: 540-347-5957

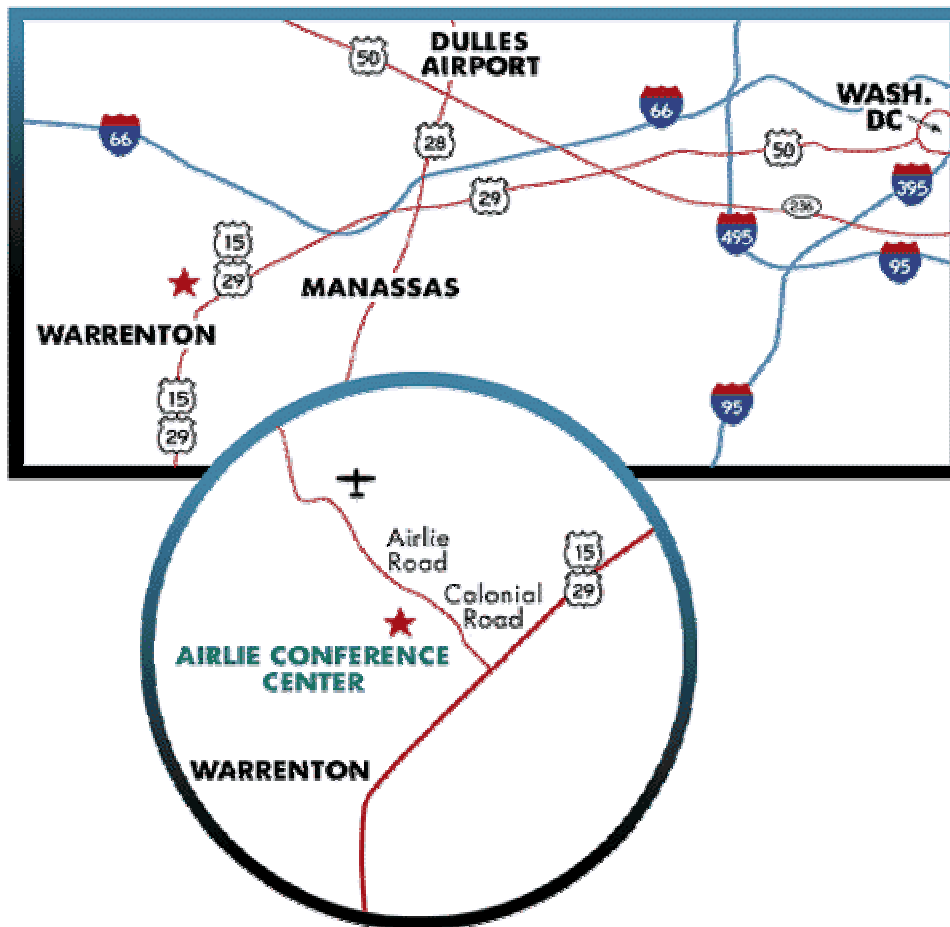
Parking is available at the Conference Center at no charge. Driving directions to the Airlie Center are enclosed for your information.

Maps of Airlie Conference Center and of the location of meeting rooms.

Information about Warrenton, VA (the closest town) and surrounding area is available at <http://www.warrentonontheweb.com/> and at Tab 6 in this Resource Binder.

Location and Driving Instructions

Map



From Washington/National Airport

Take I-66 West to exit 43A (Gainesville/ Warrenton) and proceed South on Rt. 29 for approximately 10 miles. Take a right at the traffic light onto Colonial Road, proceed for two miles, Colonial Road will turn into Airlie Road. Cross a one-lane stone bridge, an immediate left will place you on the drive to Airlie House.

From Dulles Internationa

Exit Dulles Airport and take Exit 9 to Rt. 28 South, follow to I-66 West. Follow above directions.

From Richmond and Points South

I-95 North to Rt. 17 North towards Warrenton. Right on Rt. 29 North. Pass all 3 Warrenton Exits. Left at Light , Rt. 605 (Colonial Road which turns into Airlie Road). Go approximately 2 miles, cross a single-lane stone bridge. Take an immediate left into main entrance.

Campus Map

Location of Meeting Rooms

Meal Services and Special Dietary Requirements

Three meals a day as well as beverage services during breaks are provided as part of the conference package paid for by OBSSR. If you have any special dietary needs, please contact Gale Quilter at TASCAN (301-315-9000 ext. 268). Only box lunches will be provided on Saturday and Sunday, August 4th and 5th.

Telephone and Internet Access

There are data ports in each guest room. You will need to bring your own laptop computer and modem for Internet connections in your guest room. Local and 1-800 calls are free as long as the call lasts less than one hour. After one hour on the line, guests will be charged 50 cents per minute. This is especially important to note when you use the phone or Internet for extended amounts of time, since you are responsible for all telephone charges. Pre-paid calling cards are available for purchase at the front desk.

In addition, one computer with an Internet connection and a printer is available in the lobby. You can use this computer for web-based e-mail.

Computer Facilities

We encourage you to bring a laptop computer, since we will be providing only limited access to computers. As just noted, one computer and printer is positioned in the lobby. We will set up at least one additional computer and printer elsewhere. To print files, you will probably have to transfer files from your computer to ours via floppy disks. So, bring some diskettes with you!

Macintosh Users: Airlie House is a Microsoft Windows environment. Make sure your Mac software can produce files that can be read by MS Word, PowerPoint, or Excel for Windows or by WordPerfect. You will have to copy files onto IBM-compatible disks (which is not a problem for recent versions of the Mac OS).

Photocopying

A photocopier is available for our use. The charge is 10 cents per page. So, if you know in advance that you want to distribute multiple copies of something, please bring them with you. (The maximum number of participants and faculty is 46.) Of course, we will make copies of materials that we produce on site during the course.

Local Medical Services

Hospital

Fauquier Hospital
500 Hospital Drive
Warrenton, VA 20186
540-347-2550 is their Main Number
In case of emergency, dial 911.

Pharmacies

CVS
Northern VA Shopping Center
Warrenton, VA 20186
540-341-4207 Store Phone
540-347-1621 Pharmacy Phone

Rite Aid Pharmacy
251 W Lee Hwy
Warrenton, VA
540-347-3020

CVS
605 Frost Avenue
Warrenton, VA 20186
540-341-2823 Store Phone
540-349-0911 Pharmacy Phone

Wal-Mart
8278 James Madison Hwy
Warrenton, VA
540-341-7561

Daily Recreation

The Airlie Conference Center is in a country-club-like setting (but *sans* golf course) and offers opportunities for country walks, biking, tennis, jogging, swimming, skeet shooting, and fishing. (Note: lifeguards are not present at the pool or the lake.) Some fitness center equipment is also available. A pleasant pub (with cash bar), complete with billiards table, is located near the swimming pool and open during the evenings.

Special recreation activities are planned for the weekend of August 4th and 5th. See *Tab 5: Recreation*.

Childcare

Please note that there are no special accommodations for children at Airlie; there are no lifeguards at pools, cribs, rollaway beds, high-chairs/booster seats, children's menus, baby-sitting services. Recreation activities are geared more toward adults; but children may enjoy some of them (e.g., biking, fishing, swimming). All children must be supervised at all times by an adult.

For liability reasons, neither the Airlie Conference Center nor the NIH can recommend specific childcare services. You may call the Fauquier County Social Services (Children's Services Department) at 1-540-347-2316 for a listing of licensed child care providers in the area. They will be more than happy to mail you a listing upon your request. However, your best option is to bring someone that you know and trust to care for your child while you are attending the Summer Training Institute.

*Summer Training Institute for Randomized Clinical Trials
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Continuing Education Credits

**Summer Training Institute on Design and Conduct of Randomized
Clinical Trials Involving Behavioral Interventions**

July 29 to August 10, 2001

Airlie, Virginia

Presented by the NIH Office of Behavioral and Social Sciences Research

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 **58** 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 **58** hours in Category 1 credit towards the AMA Physician's Recognition Award.

To obtain certification of attendance, please complete this form. You may leave it at the continuing education table at the conclusion of the conference or mail the form to:

Ms. Gale Quilter
TASCON, Inc.
1803 Research Blvd., Suite 305
Rockville, MD 208850
Phone: 301-315-9000, ext. 268

Introduction, Organization, and Logistics

Daily hours attended: I have attended the following session(s) of the Summer Institute on Design and Conduct of Randomized Clinical Trials Involving Behavioral Interventions:

Date	Maximum Program Hours Eligible for CME/CPE.	Hours attended (CME/CPE Claimed)
Sunday, July 29, 2001	2	
Monday, July 30	5.5	
Tuesday, July 31	5.5	
Wednesday, August 1	5.5	
Thursday, August 2	5.5	
Friday, August 3	5.5	
Sunday, August 5	2	
Monday, August 6	5.5	
Tuesday, August 7	5.5	
Wednesday, August 8	5.5	
Thursday, August 9	5	
Friday, August 10	5	
Total	58	

Certificate of attendance should be mailed to (please print):

Name- Last	First	Middle Initial	Professional Degree	Date of Birth (Month/Day/Year Required for CME)
Phone	E-mail	Organization	Institute/Center	Dept/Branch
Street Address/P.O. Box				
City	State	Zip Code		

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Evaluating the Course

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 educational event (e.g., lecture, study group) and return the completed forms by the end of the Summer Training Institute. Also, please provide us with your written comments on the course as a whole by answering the following questions. Thank you.

Comments (Please use extra pages as needed.)

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?
5. How helpful were the Study Groups? Do you have any suggestions for improving them?
6. What about the Required and Suggested Readings? Too many, too few? Were they relevant to the lecture and course's subject matter?

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Expenses

OBSSR is paying for your travel and living expenses (room and board) while you are attending the Summer Training Institute. You are responsible for telephone and incidental expenses. (Local and 1-800 calls are free as long as the call lasts less than one hour. After one hour on the line, guests will be charged 50 cents per minute.) OBSSR will reimburse you for ground transportation costs by taxi or similar means of transportation between your home/office and the Airlie Center. Receipts are necessary only for any one cost that exceeds \$75, including taxi fares and airport parking.

The additional adult (spouse) rate is \$100/person/day. This rate also applies to babysitters. This rate includes a guestroom shared with you (the meeting participant), 3 meals per day, and use of Airlie's facilities. Airlie always tries to assign couples to a double-occupancy room, one with two double beds instead of one double-bed. Teenagers (16 and over) can be accommodated at regular "spouse" rates.

For NIH/OBSSR attendees who elect to bring children under 16 years of age and who want to house the children in their guestroom with them, the cost will be \$75/child/day. There is no charge for infants. Note: If there are more than 2 occupants per room, someone will need to share a double bed with someone else. The maximum number of occupants per room is 2 adults and 2 children. Children under 16 must stay in a room with an adult.

If you intend to drive to the meeting, you will be reimbursed at the rate of **\$0.345/mile**, plus any tolls, for the use of your private auto. Reimbursement of long distance travel by private automobile cannot exceed the amount to be paid for air or rail travel by the most direct route at the lowest reasonable fare. It is necessary to keep odometer readings and obtain receipts for parking and tolls. Car rental is not a reimbursable cost without prior written approval.

Please note: In accordance with U.S. Government travel regulations, if you are traveling to the meeting from within 50 miles of your home, OBSSR can reimburse you only for your mileage.

Reimbursement Procedures

Please use the provided *Participant Travel Reimbursement Form* to request payment of your out-of-pocket expenses. If you have not already completed the *Request for Taxpayer Identification Number and Certification*, please contact Gale Quilter at TASCAN.

TASCAN will reimburse your long distance travel and local ground transportation expenses and provide a meal per diem for days when you are not at the Conference Center. You should have no other expenses. Please note that travel to local attractions, restaurants, and shopping areas is not a reimbursable expense.

You should receive payment within 30 days after TASCAN receives your correctly completed Participant Travel Reimbursement Form. ***Please remember to: (1) Retain and forward all required receipts, and (2) Mail the original signed and dated forms to TASCAN. Faxed forms are not acceptable.***

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