Winter 2004

GATHERING FRIENDS

FRI THE NEWSLETTER OF FRIENDS RESEARCH INSTITUTE

PROJECT PAC+

MAKES A DIFFERENCE IN THE LOS ANGELES COMMUNITY

PAC Exchange Store at Genesis.

"A healthy lifestyle for mother and child means a stronger community and a brighter future."

With this sentiment at the heart of the work, Dr. Leslie Amass, FRI Principal Investigator for the Pregnant and Clean Plus Project (Project PAC+), strives to promote a healthier lifestyle for mothers and children in the Los Angeles community.

Project PAC+ is a free, non-profit, outpatient research program for women who smoke cigarettes and use other drugs. The goals of the program are:

- To increase healthy outcomes in female smokers in substance abuse treatment;
- To promote a smoke-free living environment for the babies and children living with them;
- To study an incentive-based treatment for reducing cigarette, alcohol, and other drug use;
- To determine whether the incentives can be financed with donated goods and services from corporate and community sponsors; and

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Project PAC+ Making A Difference

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- To create an instruction manual for establishing similar community supported programs in clinics throughout the United States.

To be eligible for the program, participants must be at least 15 years old, current cigarette smokers and agreeable to the project's requirements. Many of the women in the project are pregnant or have young children living in their homes.

The program operates at the Shields for Families substance abuse clinics, located in two disadvantaged neighborhoods of Los Angeles. Shields provides pre and post-natal services and parenting classes to all of their clients. In addition, the women in the program earn vouchers, redeemable for a variety of goods and services, in exchange for not using cigarettes, alcohol, and other drugs during treatment. Goods and services are donated by both corporate and community sponsors and can be redeemed at a voucher store known as the PAC+ Exchange. Some examples of products that can be redeemed are the following: non-perishable food, personal care products, pharmacy items, clothing, baby goods, toys, medical services, and store certificates.

Although the research component of Project PAC+ is funded by a grant from the National Institute on Drug Abuse, the program relies on fundraising and the generous support of private contributors to provide the goods and services that are redeemable at the PAC+ Exchange. Recently, the program received much acclaim and financial support in being chosen as the beneficiary of proceeds obtained through a fashion show sponsored by Naissance on Melrose during the Los Angeles Fashion Week.

Naissance on Melrose is an upscale maternity clothing boutique in the heart of trendy Melrose that provides its customers with an array of hip and stylish clothes, and also serves as a resource center for moms-to-be. The store has been a contributor to the PAC+ project since August 2000, donating women's clothing and books on pregnancy.

On October 29, 2003 Naissance on Melrose hosted their Spring 2004 fashion show in Downtown Los Angeles. In addition to displaying new designs for the upcoming spring season, the event also served as a fundraiser for Project PAC+.

Project PAC+ has also had fundraising success with the March of Dimes, Shelter Partnerships, and Trader Joes, who each donate products and services to the project on a regular basis. Project PAC+ has received over $177,000 in product donations to date. The program's fundraising efforts and results have been accepted for publication in the Journal of Clinical and Experimental Psychopharmacology.

Preliminary analyses of Project PAC+ indicate that women receiving vouchers reduce their use of cigarettes over three times more than those who do not. Thus, this community sponsored voucher program directly helps to improve the overall health of women and reduces their children's exposure to second-hand smoke. Dr. Amass and her invaluable staff are on the way to creating a stronger community, and a brighter future for its members.

If you are interested in making a donation to Project PAC+, please contact Tara Samiy, at 310-312-0500 x386 or via email, tsamiy@friendsresearch.org. For further information about the research program, contact Dr. Leslie Amass at 310-312-0500 x352, or via email, lamass@friendsresearch.org.

Gathering Friends *is a publication of Friends Research Institute, Inc. (FRI). Please forward any correspondence to Julie Simon Agetstein, FRI, 505 Baltimore Avenue, P.O. Box 10676, Baltimore, MD 21285.*

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Contributor: Paula Thomas

Ask The IRB Staff

What is a full board review?

In reviewing research protocols involving human participants, an Institutional Review Board (IRB) can employ one of three types of review procedures, including exempt, expedited, or full board review, in compliance with the Department of Health and Human Services (DHHS) regulations for the protection of human participants. Research that involves prisoners, more than minimal risk, or is not covered by the expedited review or exempt categories will require full board review. At FRI, most new studies are reviewed using this procedure, to ensure a thorough review and to provide the greatest protection to our research participants.

For full board initial reviews, the Principal Investigator must submit a completed submission check-off list, application for study review, detailed research protocol (including biographical sketch, literature cited, and budget information), informed consent document, certification of education in research ethics and the protection of human subjects, financial disclosure form, subject recruitment material, and a copy of the instruments that will be used. When necessary the PI must also submit the following: supplementary application for vulnerable populations, Investigational New Drug (IND) form, Investigational Device Exemption (IDE) form, indications for IND and IDE form, investigational drug information record, investigator's brochure, FDA 1572, supplementary application for research involving DNA/Tissue/Sample Banks, and federal grant application.

The IRB will conduct a systematic review of this material, discussing the risk/benefit analysis, informed consent, selection of subjects, privacy and confidentiality, monitoring and observation, additional safeguards, incentives for participation, methodology, and the purpose and background of the protocol. Once the risks have been identified, the IRB will assess whether the research presents greater than minimal risk, and the timeframe for continuing review. Typically, the IRB will review a minimal risk study once a year, and a greater than minimal risk study every six months.

For full board continuing reviews, the PI must submit a completed submission check-off list, application for continuing review, progress report, list of all AEs since the last review, latest approved protocol, and the latest approved informed consent document. If amendments or addendums are being requested at this time, the PI must also submit an explanatory letter of the change, modified consent document, and a modified protocol.

The IRB will review this material and discuss whether the risks and benefits are as anticipated in the initial review, if any unforeseen problems have occurred, if any new risks or benefits have been identified, if the number of subjects accrued is consistent with the IRB approved number, if the consent form requires revision, and if the procedures for data monitoring are adequate.

All protocol amendments/addendums, and consent form amendments/addendums, must also be reviewed by the IRB; however, minor changes in previously approved research during the period for which approval is authorized can be reviewed via the expedited review procedure.

In a full board review, the IRB can vote to approve, approve with contingencies, disapprove, or defer a review until another meeting. A majority vote is needed to pass a motion, and a quorum must be maintained throughout an entire IRB meeting. If an IRB member has any significant interest in the outcome of the study, s/he will abstain from voting. An IRB member with a conflict of interest related to the study will not participate in the discussion of the study.

For more information regarding specific research please contact the IRB staff, Julie Agetstein on the East Coast and RoseAnn Fleming on the West Coast. All of the aforementioned IRB forms can be accessed on FRI's website at http://www.friendsresearch.org/IRBforms.html.

Farewell to an Esteemed FRI Board Member

It is with regret that FRI announces the resignation of an esteemed member of its Board of Directors. After slightly over four years of service to FRI, Clyde R. Burke will attend his last meeting as a Board member in February of 2004. Due to obligations to serve his own company, Mr. Burke will no longer have the time to commit to FRI in the manner that he feels it deserves. Throughout his tenure at FRI, Mr. Burke has played a very active role in Board matters and has provided very wise counsel in a number of areas. He will be sorely missed. FRI wishes Mr. Burke much success in all of his future endeavors.

New Members Bring Exceptional Experience to FRI's Institutional Review Boards

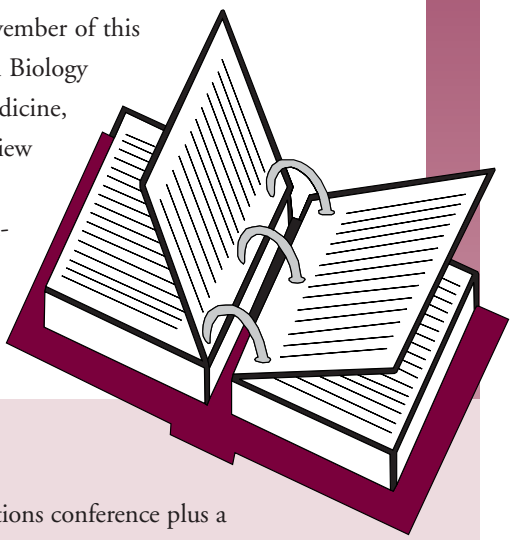
FRI is pleased to announce the appointment of one new member to its West Coast Institutional Review Board (IRB), and four new members to its East Coast IRB. All five of the new members bring a unique perspective and exceptional experience to FRI's IRBs, thus providing greater protection to FRI's human research participants.

Ms. Debbie Green, who is a Resident Case Manager at the Tarzana Treatment Center in Reseda, became a West Coast IRB member in November 2002. Because of her close working knowledge of prison conditions and the life of a prisoner, Ms. Green is one of the prisoner advocates on the IRB, who pays close attention to the special needs of this vulnerable population.

The East Coast IRB welcomed four new members. Cornel Rogers, P.A., B.Sc., Allen Walker, M.D., and Steven Williams, Ph.D. joined the IRB a little over a year ago and have since provided invaluable service to the protection of FRI's human research participants. Mr. Rogers, a Physician's Assistant to the incarcerated population of the Baltimore County Detention Center and primary care provider to incarcerates of city, county and state correctional facilities, is one of two Prisoners' Advocates on the East Coast IRB. Dr. Walker, Medical Director of the Pediatric Emergency Department of Johns Hopkins Children's Center, serves as the Children's Advocate. Dr. Williams, a licensed clinical psychologist and Director of Industry and Market Research at the American Society of Associations Executives, brings knowledge of clinical psychology, research design and statistics to the IRB.

The newest member of the East Coast IRB, Hendree Jones, Ph.D., was appointed in November of this year and has already proved to be a tremendous asset. As an Assistant Professor of Behavioral Biology and Program Director of Cornerstone at the Johns Hopkins University (JHU) School of Medicine, and Director of Research at the Center for Addiction and Pregnancy at Johns Hopkins Bayview Medical Center, Dr. Jones serves as the specialist in drug abuse research.

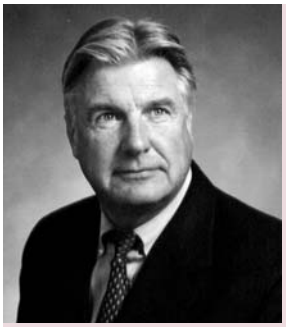
The new IRB members have already brought fresh insight, enthusiasm, expertise, and sensitivity to FRI's IRBs, and we look forward to their continued dedication and service. FRI appreciates all of its IRB members who help to advance science and research at FRI, while protecting the very people that make research possible.



SAVE THE DATE: Upcoming FRI Conferences

- FRI will be sponsoring a 2-day comprehensive national human research subjects protections conference plus a 1-day pre-conference IRB Workshop: *Fundamentals of Human Research Protections (FHRP™)*, with the Office of Human Research Protections, Department of Veterans Affairs, Florida Agricultural Mechanical University, Florida State University, Florida Department of Health, and the Food and Drug Administration. The conference entitled, *"Recognizing and Protecting Vulnerable Subjects: Theory, Practice, and Compliance,"* will be held at The Peabody Hotel in Orlando, Florida March 31–April 2, 2004.
- FRI is sponsoring its sixth national conference on biomedical ethics. The conference entitled, *"Ethics of Human Cloning"* will be held in San Francisco, California, May 25–26, 2004 and will be jointly sponsored by FRI and Stanford University. There will be a one-day pre-conference workshop on *Advanced Methods in Human Research Protections (AMHRP™)*, May 24, 2004.
- FRI is also administrating the following Veterans Administration (VA) conferences:
  - VA Nurses Surgical Quality Improvement Program (NSQIP) Conference in San Antonio, Texas, March 22–24, 2004
  - VA Diabetes Educators Meeting, Indianapolis, Indiana, August 9–10, 2004
  - VA Surgical Symposium, Washington, D.C., September 2004

For more information on these and other upcoming conferences, please visit FRI's website or contact the conference division at (410) 763-7620.



A Message from the Executive Director

I am pleased to announce that John M. Roll, Ph.D. has recently accepted the newly created position of Scientific Director. The duties of the Scientific Director consist of planning and participating in the ongoing prevention and treatment research programs, developing funding sources for research projects, assisting in the development of FRI's mission, and in coordinating research policy for FRI. The Scientific Director will raise public awareness of FRI, integrate and support new investigators, and provide overall scientific leadership for the organization.

Dr. Roll received his Ph.D. in Experimental Psychology from Washington State University in 1994. In 1997 he joined the faculty of Wayne State University as a member of the Research Division on Substance Abuse where he also had an appointment at the Detroit VA hospital. He left Detroit to accept positions with UCLA and FRI in December of 1999.

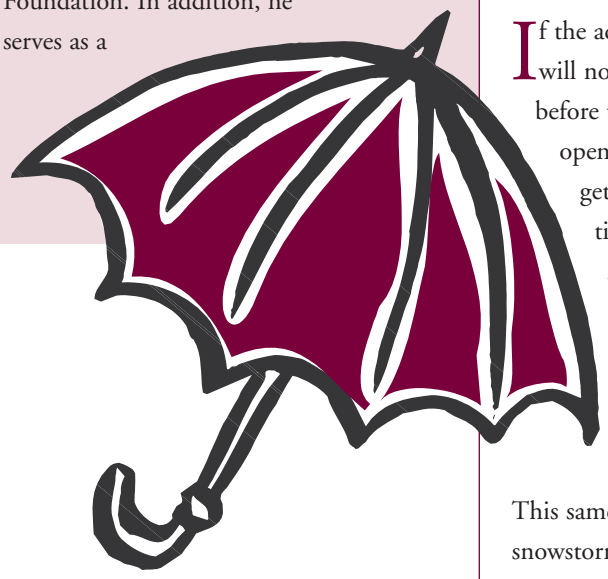
Dr. Roll has been an author or co-author on over 80 published journal articles, abstracts, and chapters. He was the Program Chair for Division 28 at the 2001 American Psychological Association's convention, is currently the Membership Chair for Division 28, and has been the Organizer of the Annual Contingency Management Working Group for the past 7 years. Dr. Roll is also a member of the Awards Committee of the College on Problems of Drug Dependence, and a member of the Research Advisory Board of the Parkinson's and Movement Disorder Foundation. In addition, he serves as a reviewer for NIH, SAMHSA and VA grant applications.

Dr. Roll is currently the Principal Investigator (PI) on a number of projects, and has served as the Pacific Node's representative to several Clinical Trials Network Committees, as well as the Pacific Node's research faculty in charge of the Motivational Incentives protocol. His primary research interests are in basic behavioral pharmacology and the development of behavioral interventions for substance abuse and related disorders.

During his tenure as a PI at FRI, Dr. Roll has served as a member of the West Coast Institutional Review Board and the Quality Improvement Committee.

In January, Dr. Roll will relocate to Mead, Washington where, in addition to his new duties with FRI, he will become the Assistant Director in Charge of Substance Abuse and Other Addictive Disorders Research at Washington State University's Spokane branch. I am confident that Dr. Roll will thrive in his new position as FRI's Scientific Director and that his leadership and extensive research experience will help us to advance science and research at FRI.

Patrick F. Bogan



Employees' Corner

FRI would like to remind the employees of its inclement weather policy, which is as follows:

If the administrative offices of FRI close due to inclement weather, employees will not be expected to come to work. If employees are not informed of a closing before the offices are scheduled to open, employees must assume that FRI is open for business. For those employees who may face substantial difficulty in getting to work because of severe inclement weather, or with family situations related to the inclement weather that prohibit leaving home at their regular time, a two hour grace period will be given, for which there will be no deduction in pay. If FRI is open and an employee makes a personal decision to be absent, time off will be charged to accrued vacation leave or accrued personal leave. This is considered FRI's Liberal Leave policy. If an employee does not have any accrued vacation or personal leave remaining, the employee's paycheck will be adjusted accordingly. This same policy exists for any type of natural disaster (flooding, earthquakes, snowstorms, etc.).

Friends Research Institute, Inc.

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Happy Anniversary!

Congratulations to this quarter's employees who have celebrated an anniversary with FRI. We appreciate your loyalty and dedication to the organization.

OCTOBER	YEARS
Timothy Kinlock, Ph.D.	24
C. James Klett, Ph.D.	14
Phyllis Lloyd	13
Dachon Carroll	9
Peter Guarino, M.D.	5
Jerry Cunningham-Rathner	4
William Purnell	4
Felicia Beanum	4
Jason Callaman	3
Michael Agar, Ph.D.	3
Marc Rose, Ph.D.	3
Chandra Porter	1

NOVEMBER	YEARS
Eleanor Bruns	24
David Hoyte	7
Marsha Swilley	7
Robert Storey	4
Michael Gordon	4
Carla Johnson	3
David Highfield, Ph.D.	2
Robert Ausby	2
Michele Ricketts	2
Ellen Kelley	2
Pamela Henderson	2
Dionna Ervin	2
Regina Willis	2

DECEMBER	YEARS
Thomas Hanlon, Ph.D.	44
Patrick Bogan	35
Donnette Randolph	8
Jessica Fradis	4
John Roll, Ph.D.	4
Erin Rotheram-Fuller	4
Luna Ester Yojay, Ph.D.	3
Elena Nieves	3
Jessica Lopez	2