Fall 2004

GATHERING FRIENDS

THE NEWSLETTER OF FRIENDS RESEARCH INSTITUTE

FRI's Medical Director Receives the 2004 Nyswander-Dole Award

On October 19, 2004 Dr. Robert Schwartz, FRI's Medical Director, was awarded the Nyswander-Dole Award at The American Association for the Treatment of Opioid Dependence's (AATOD) 2004 National Conference, in Orlando, Florida. AATOD was founded in 1984 to enhance the quality of patient care in treatment programs by promoting the growth and development of comprehensive methadone treatment services throughout the United States. The organization is committed to upholding the standards of quality comprehensive treatment first developed by Drs. Marie Nyswander and Vincent Dole in the mid-1960's.

Dr. Robert Schwartz

Fondly called "The Marie" after Dr. Nyswander, the Nyswander-Dole Award was first presented in 1983 to recognize extraordinary work and service in the opioid treatment field. Recipients are selected by their peers from each region in the United States with at least one international. Recipients of a Marie are not only recognized for their outstanding contributions to methadone treatment, but the award brings with it a responsibility to methadone treatment and particularly in treating patients with dignity and respect. Dr. Schwartz was one of 10 recipients, from all over the world this year, honored with a Marie at the 2004 conference.

Dr. Schwartz has been a constant and commanding proponent of drug abuse treatment for 15 years. As a treatment provider, researcher and advocate, he has been successful at increasing access to methadone maintenance treatment in both the community and within prisons. He served as Director of the University of Maryland School of Medicine's Division of Alcohol and Drug Abuse prior to joining Friends Research Institute. At Maryland, he was responsible for the Division's teaching, patient care and drug abuse research programs. During his work at Maryland, he more than doubled their clinics' treatment capacity, developed a new methadone program to continue medically-ill hospital inpatients into outpatient therapy, opened a women's program and an intensive outpatient program, and evaluated a long-standing medical maintenance program at Man Alive, a drug rehabilitation center in Baltimore.

As the Medical Director of FRI his research has explored the effectiveness of interim maintenance treatment and the use of methadone treatment with individuals on probation. He is currently working on studies, which examine reasons for entry and retention in methadone treatment, effective ways to retain outpatients in

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Medical Director Receives Award

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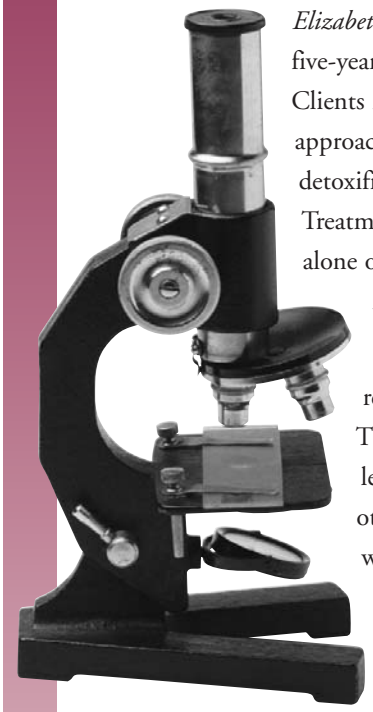
buprenorphine withdrawal, and the provision of methadone treatment for pre-release inmates. In addition, through the Open Society Institute-Baltimore, Dr. Schwartz promotes the welfare of opioid dependent individuals by supporting projects that strengthen Baltimore's treatment system, advocate for treatment-on-demand, improve relationships between communities' associations and treatment programs, examine zoning restrictions on program operation, enhance counselor training and recruitment, integrate buprenorphine treatment with primary care, and increase the use of best practices in opioid agonist treatment.

FRI congratulates Dr. Schwartz on being honored with this prestigious award.

New Research at FRI

FRI is pleased to announce that the following investigators have recently received grants from the federal government.



Elizabeth Katz, Ph.D., FRI Principal Investigator on the East Coast at the Social Research Center, received a five-year grant from the National Institute on Drug Abuse (NIDA) entitled, "Engagement of Detoxification Clients into Long-Term Treatment." The study is designed to evaluate the effectiveness of three counseling approaches for improving transition of substance dependent patients from a 30-day outpatient buprenorphine detoxification into long-term drug-free treatment. The study will compare routine treatment at the Harambee Treatment Center (an outpatient, drug-free clinic in Baltimore City) with Intensive Role Induction, either alone or combined with case management. The Co-Investigators on this project are *Barry Brown, Ph.D.*, and *Robert Schwartz, M.D.* The study began on August 1st of this year and will conclude in July 2009.

Thomas Hanlon, Ph.D., FRI Principal Investigator on the East Coast at the Social Research Center, received a five-year grant from the National Institute of Nursing, entitled, "Village Model of Care." This research examines the application of a multifaceted after-school approach, within an alternative learning setting. It is designed to prevent both the initiation and escalation of alcohol, tobacco, and other drug use, risky sexual behaviors, and violence among high-risk inner-city African-American youth who have been expelled from traditional public schools because of violence or other serious rule infractions. The Co-Investigators on this project are *Steven Carswell, Ph.D. Candidate*, and *Betsy Simon, M.S.* The study began on September 1st of this year and will conclude in May 2009.

Donnie Watson, Ph.D., FRI Principal Investigator on the West Coast, received a two-year grant from NIDA, entitled, "Substance Use and HIV Prevention." The purpose of this project is to develop and pilot test a new intervention that results from the adaptation of two evidence-based pre-existing culturally and gender sensitive interventions shown to reverse negative trajectories toward substance use and HIV risk behaviors among at-risk adolescents. This project will evaluate the feasibility of delivering the intervention to a group of youth attending unique alternative schools in correctional settings. The Co-Investigator on this project is *Marguerita Lightfoot, Ph.D.* The study began on September 25th of this year and will conclude in June 2006.

John Roll, Ph.D., FRI Scientific Consultant and Principal Investigator on the West Coast, received a four-year grant from NIDA entitled, "Contingency Management: Duration Effects." The major goal of this project is to determine what the optimal duration of a contingency management intervention for stimulant abuse should be when delivered in conjunction with a psychosocial treatment package. The Co-Investigator on this project is *Paul Brethren, M.A.*, and the Project Director is *Joy Chudzynski*. The study began on July 15th of this year and will conclude in June 2008.

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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Ask The IRB Staff

Does FRI's IRB Department have a policy regarding International Research?

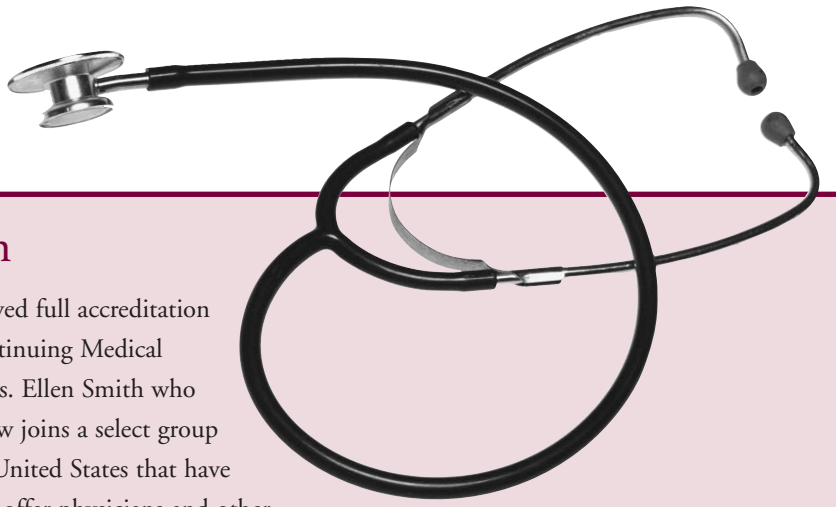
FRI recently approved an IRB International Research Policy to ensure the protection of FRI's human subjects in international research studies and to comply with the Office for Human Research Protections (OHRP) directives requiring local context review of such studies. This policy will now apply to the review of all FRI research studies conducted outside of the United States. "Outside of the United States" means research occurring outside of the 50 states and the United States territories.

The following bullets highlight some of the important elements of the new International Research Policy:

- Protocol review and approval is required by the outside country's IRB, Ethical Review Committee, or equivalent organization, and FRI's IRB.
- All of the FRI IRB policies for research studies conducted within the United States apply to international research.
- The policy provides a list of the additional information that should be included in international research protocols, such as an explanation of the cultural differences that influenced the study design and the consent process, the rationale for conducting the study with an international population, and information regarding the host country's IRB.
- It is the practice of the FRI IRB to give full board review to all research studies conducted outside of the United States that include human subject contact. Each protocol will have a local context review, by a local context consultant, who is familiar with the customs and culture of the study population. The reviewer will attend, in person or via telephone, convened FRI IRB meetings in which the protocol is reviewed for the first time.
- For studies that involve no contact with subjects and that are minimal risk, expedited review may be granted by the FRI IRB. If a minimal risk study receives expedited review, a consultant familiar with the local context will be asked to provide to a reviewer a written evaluation for local context review.
- A protocol will have only one local context review unless there are significant changes in the protocol or the risks to subjects.

The policy also provides guidance for protocols that involve special IRB considerations, such as, studies involving populations that have no written language, studies involving populations that utilize group consent, and studies involving minors.

The full International Research Policy can be accessed on FRI's website, or a copy of it can be obtained from the IRB Department.



Continuing Medical Education

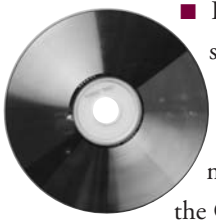
FRI is pleased to announce that it has recently received full accreditation from the ACCME (Accreditation Council for Continuing Medical Education), thanks in large part to the hard work of Ms. Ellen Smith who was employed at the FRI Conference Division. FRI now joins a select group of only 700 research and medical organizations in the United States that have received this distinction. This means that FRI can now offer physicians and other professions CME credits for its educational presentations.

NIH Grant Enabled FRI To Enrich its Human Research Protections Program

A two-year human subjects research enhancements grant, which was awarded to FRI from the National Institutes of Health (NIH), concluded in August of this year. The award was intended to provide short-term support for institutional activities that will strengthen oversight of human subjects research at institutions. FRI is one of 142 institutions that received this grant. Patrick F. Bogan, Executive Director, was the Principal Investigator, and Ned Rubin, Director of Quality Improvement, was the grant's administrator.

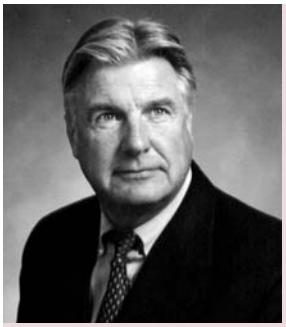
This NIH grant enabled FRI to enrich its human research protections program over the past two years. Year two of the grant also made it possible for FRI to further the human research protections program at the Florida Department of Health's IRB, which FRI has a contract to manage. Here is a sampling of what the award has afforded FRI the opportunity to do:

- Write, produce, manufacture, and distribute a video in DVD/VHS format, with webstream component, entitled "What to Know About Informed Consent." The video is an introduction to research, the consent process, and what it means to be a research participant in general. It is intended to be used as a teaching/training tool, or as an introduction to the consent process for prospective research participants. Hopefully, the video will be shown to potential research participants to supplement and enhance the grant process. The target audience of the video is prospective research participants, Principal Investigators, medical, nursing, and health science students, undergraduate and graduate students, research staff, IRB members and staff, and the lay public;
- Develop and provide educational programs to IRB members, IRB staff, PIs, and research staff, on Fundamentals of Human Research Protections™ (FHRP™), Advanced Methods in Human Research Protections™ (AMHRP™), and the HIPAA privacy and security rules;
- Purchase and distribute IRB and HIPAA manuals/handbooks for IRB staff and IRB members at FRI and Florida Department of Health;
- Fund an online HIPAA training program (HC-Professor™) for FRI and Florida Department of Health staffs;
- Fund an online human research protections course (CITI) for FRI's researchers, research staff, and IRB members;
- Fund attendance by FRI's IRB members and staff, and Florida Department of Health's IRB members and staff, at various seminars and workshops/conferences on human research protections;
- Develop presentations and handouts for internal and external use;
- Develop additional software to track "external" (i.e., non-FRI/Florida Department of Health) serious adverse events;
- Perform IRB, QI, Compliance, and HIPAA audits and monitoring;



- Implement a "paperless" IRB system at the Florida Department of Health, and help fund the software and hardware for IRB members and staff to utilize it. This system allows the researchers to make online IRB submissions; for the IRB staff to distribute CDs containing all of the necessary submission materials, rather than dense packets of paper to the IRB members; and for IRB members to review and make changes to the submissions directly to the CD-ROM both prior to and during IRB meetings.

Thus, the NIH grant was instrumental in enhancing the human research protections program at FRI, the Florida Department of Health, and 141 other institutions across the country. FRI is hopeful that NIH will be able to offer such an important program again in the future. The National Center for Research Resources of the NIH is seeking to issue another competitive bid request next year for an additional round of funding.



A Message from the Executive Director

FRI recently conducted a survey of its investigators to determine their satisfaction with services and to seek their feedback on areas where improvements could be made. Participation was excellent as 82% of the investigators included in the survey responded. I appreciate the time and suggestions of those who responded and offered their constructive assessment.

The survey asked the investigators to rate the following issues in order of importance, and then to rate the actual service they receive from FRI on each: timeliness of FRI's response to your requests and inquiries, breadth of services offered, overhead rate charged on grants being administered, accessibility of FRI's CEO, role of FRI's Institutional Review Boards (IRB), performance of payroll/administrative functions/personnel, availability of human resources support, support for grant preparation and submission, training seminars in such areas as privacy rules/sexual harassment/etc., financial support during grant development and preparation, and assistance with budget and financial matters.

The survey also asked investigators what additional services they would like to see FRI offer, if they would be willing to talk to prospective investigators on behalf of FRI, and if they have any additional comments, observations, or constructive suggestions.

The survey results indicate that "timeliness of response" and the "role of the IRB" were considered to be the most important of FRI's services. In all service categories, FRI's service was rated a 3.22 (on a 4 point scale) overall. The following services received the highest ratings: "breadth of services (3.79)," "role of the IRB (3.69)," and "timeliness of response (3.46)."

For the most part, there was a positive correlation between the importance of an issue to the investigators and their evaluation of FRI's services. This seems to indicate that we are anticipating the needs of our investigators, and working hard to ensure that these needs are met with the highest degree of satisfaction.

Additionally, investigators made several excellent suggestions for areas of improvement. We will thoroughly review and evaluate these comments, observations, and constructive suggestions, and will use this information to plan for the future, to make improvements where they are needed, and to keep everyone at FRI working to provide the best service possible. Once again, our sincere gratitude to the investigators who took the time to complete this survey and help FRI assess its services. You are helping us to create a more positive working environment for everyone at FRI.

Patrick F. Bogan

Congratulations!

FRI would like to congratulate Wanda L. Cross, Financial Administrator, for 40 years of service to FRI beginning June 24, 1964. FRI recognizes and appreciates her dedication, loyalty, and continuous hard work on behalf of the organization. Congratulations to Wanda on this noteworthy accomplishment.

Employees' Corner

FRI wishes you a very safe and happy holiday season. The 2004–2005 Holiday Schedule is as follows:

Thanksgiving Day	Thursday	November 25, 2004
Friday after Thanksgiving	Friday	November 26, 2004
Christmas Eve	Thursday	December 23, 2004*
Christmas Day	Friday	December 24, 2004*
New Year's Eve Day	Thursday	December 30, 2004*
New Year's Day	Friday	December 31, 2004*
Martin Luther King Day	Monday	January 17, 2005
President's Day	Monday	February 21, 2005
Memorial Day	Monday	May 30, 2005
Independence Day	Monday	July 4, 2005
Labor Day	Monday	September 5, 2005

**Holiday falls on a weekend. The date listed is the day that the holiday will be observed for purposes of FRI's holiday schedule.*

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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.

JULY	YEARS
Ronald Maith	13
Roberta Mosby	7
Cathy Reback, Ph.D.	7
Carol Bondyra	4
Maureen Keating	2
Zoreh Davanipour, Ph.D.	1

AUGUST	YEARS
Teal Beatty	15
Esther Boyd	14
Emily Sears	9
Tony Siwak	8
Carolyn Roeth	8
Alvin Mauerhan	5
Tara Samiy	4
Heather Reisinger, Ph.D.	4
Sharon Kelly	4
Lei Zhang, M.D.	3
Bernard Fowlkes	3
Nichelle Rozier	2
Lisa Shihadi	2

SEPTEMBER	YEARS
Michele Hipsley	18
Patricia Currier	18
Faith Ellis	14
Carey Boyd	14
Barry Brown, Ph.D.	8
Leanne Zufall	8
Collin Ring	7
April Maith	7
Mitchell Cohen	7
Christie Thomas	7
Stacy Blake	5
Eugene Moynier	3
Tennille Rivera	3
Susan O'Neil	2