

FGATHERING FRIENDS

FRI THE NEWSLETTER OF FRIENDS RESEARCH INSTITUTE

SRC Investigator Receives Prestigious PATHWAY TO INDEPENDENCE AWARD

FRI is pleased to announce that *Steven Carswell, Ph.D.*, Research Scientist with SRC since March of 1997, recently received a Pathway to Independence (PI) Award (K99/R00) from the National Institutes of Health (NIH), which is the first award of this kind for FRI. This is one of the most prestigious awards that a young investigator can obtain at this stage in the research career. For this submission in particular, NIH received almost 900 applications but funded approximately 58, with FRI and Johns Hopkins University being the only two institutions in Maryland to receive funding. In addition, FRI is one of only two private research institutions to receive such funding. Moreover, of the 58 awardees, only a handful received funding for social research and Dr.

Carswell's award was one of them. He will be studying risk factors for HIV among urban African American youth.

The primary, long-term, goal of the PI program is to increase and maintain a strong cohort of new and talented NIH-supported independent investigators. This program is designed to facilitate a timely transition from a mentored postdoctoral research position to a stable independent research position with NIH or other independent research support at an earlier stage in the research career.

Eligible Principal Investigators include outstanding postdoctoral candidates who have a clinical or research doctorate and who have no more than 5 years of postdoctoral research training at the time of application.

The Pathway to Independence Award provides up to 5 years of support consisting of two phases. The initial 1–2 year mentored phase will allow investigators to complete their supervised research work, publish results, and search for an independent research position. The second, independent phase, years 3–5, will allow awardees who secure an assistant professorship, or equivalent position, to establish their own research program and successfully apply for an NIH Investigator-Initiated (R01) grant. The R01 is the major means by which NIH supports individual scientists in the field.

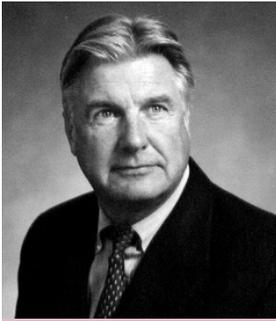
This program features a new opportunity for promising postdoctoral scientists to receive both mentored and independent research support from the same source, and FRI is proud that Dr. Carswell has received this prestigious award.



Steven B. Carswell, Ph.D.

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A Message from the President

Currently, one of FRI's foremost focal points is to help foster an exchange of ideas, talents, and research efforts between the West Coast and the East Coast Investigators, and to familiarize the Board of Directors, Investigators, and Staff with each Investigator's work and talents. At FRI, our talented Investigators are working on a plethora of research projects that vary from heroin addiction to schizophrenia to substance use and HIV prevention among Native Americans. Thus, the Board of Directors and I feel that as a research institution, we can benefit from learning about the expertise and current research objectives of each Investigator, and possibly open up the doors to some collaborative research endeavors between Investigators on both coasts.

To help facilitate this objective, FRI will be sponsoring *A Dialogue of Research and Treatment Information* symposium on April 26th on the East Coast. At the symposium, three Investigators, **Cathy Reback, Ph.D.** from the West Coast, **Robert Schwartz, M.D.** from the East Coast, and **Elizabeth Katz, Ph.D.** from the East Coast, will give presentations on their current research endeavors and areas of expertise. The symposium will serve as the first step of an exchange of ideas between East and West Coast

Investigators, and will help familiarize the Board of Directors and Staff with the various research accomplishments that are taking place throughout FRI. It is my hope that in the fall of this year, we will organize a similar symposium on the West Coast to showcase several other of our talented and hard-working Investigators, and to involve our West Coast Research and Administrative Staff, as well as members of the Board of Directors.

Exciting opportunities are abounding at FRI, and I am looking forward to the ongoing sharing of research ideas and talents among all facets of the organization. I strongly believe that this initial step will help foster a culture of understanding and respect of each others' work, and help cultivate a strong support system between the West Coast and East Coast Investigators and their Research Staff.

—Patrick F. Bogan

WELCOME!

Welcome to FRI's new employees, since the last edition of the newsletter. We look forward to many productive years together.

12/11/06	Stephanie Cleaver , Counselor at Rancho Cucamonga	3/5/07	Meda Barker , Research Assistant at Social Research Center
12/11/06	Tia Owens , Housing Assistant at Safe House	3/5/07	Jason Tomasian , Research Assistant at Van Ness Recovery House
1/3/07	Erin Rosier , Addictions Counselor at Epoch Counseling Center, Catonsville	3/16/07	Tamika Simms , Data Editor at Social Research Center
1/9/07	Twila Beck , Research Assistant at Social Research Center	4/2/07	Malene Kambon , Intensive Outpatient Counselor at Epoch Counseling Center, Essex
2/9/07	Marie Guptill , Administrative Coordinator at Integrated Substance Abuse Program, South		

Research Scientists' Dissertations Published

FRI would like to congratulate the following Social Research Center (SRC) researchers whose dissertations were published: **Steven B. Carswell, Ph.D.** and **Michael S. Gordon, D.P.A.**

Steven Carswell, Ph.D., Research Scientist with SRC since March of 1997, recently received a Doctorate of Philosophy in Sociology from American University. His dissertation was recently published as a book entitled, "Delinquency among African American Youth," by LFB Scholarly Publishing of New York. LFB Scholarly offers monographs presenting the best new scholarship in targeted fields in the social sciences.

The book details the findings of Dr. Carswell's dissertation, which utilized a cross-sectional design and a structural equation modeling statistical approach to evaluate the viability of four models in explaining the relationships among parental attachment, family socioeconomic status, and deviant peer relationships in risk behaviors and delinquency among urban African American youth. Archival data obtained from 536 African American students, consisting of 260 males (48.5%) and 276 females (51.5%) who were 12–14 years of age, were examined. Significant findings indicated that higher family socioeconomic status was related to decreased youth participation in risk behaviors and higher parental attachment was related to decreased youth involvement in both deviant peer relationships and delinquency. Moreover, higher youth involvement in deviant peer relationships was related to higher participation in both risk behaviors and delinquency. Finally, higher youth participation in risk behaviors was related to higher participation in delinquency. The findings from this study contribute to the growing body of knowledge concerning the role that risk and protective factors play in the development of deviant behaviors among youth.



Steven B. Carswell, Ph.D.

Michael Gordon, D.P.A., Research Scientist with SRC since November of 1999, recently received a Doctorate of Public Administration from the University of Baltimore. His dissertation entitled "Correctional Officer Control Ideology: Implications for Understanding a System," has been published in *Criminal Justice Studies: A Critical Journal of Crime, Law and Society*, 19 (3) 225–239. He also has a second article from his dissertation titled, "The Examination of Correctional Officers' Organizational Commitment" in press in the *Journal of Professional Issues in Criminal Justice*.

This study examined the attitudes and beliefs of 189 correctional officers at four Maryland State prisons representing various security levels regarding the control of inmates using the Correctional Control Ideology Scale (CCIS). Correctional officers reported moderate levels of custodialism. In the bivariate analysis, African American and female officers reported lower CCIS scores. In the multivariate analysis, being African American and working the evening shift were predictors of lower CCIS scores. These findings indicate that a more thorough understanding of race and gender are important in conceptualizing work force attitudes towards treating inmates within the prison environment.



Michael S. Gordon, D.P.A.

FRI congratulates Drs. Carswell and Gordon on their accomplishments.

Ask The IRB Staff

What is FRI's Serious Adverse Event (SAE) Reporting Policy?

If adverse consequences, unanticipated problems, or unexpected side effects are encountered in the course of the study, or new information becomes available which could change the perception of a favorable risk/benefit ratio, the investigator is responsible for informing the IRB PROMPTLY. Based on this information, the IRB may need to reconsider its approval of the study, require modifications to the study, or revise the continuing review timetable.

Definitions

'Unanticipated Problems' include any incident/experience/outcome that meets all of the following criteria:

- (1) Unexpected given (a) the research procedures that are described in the protocol-related documents; and (b) the characteristics of the subject population being studied;
- (2) Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the event may have been caused by the procedures involved in the research); and
- (3) Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

An SAE is one of the following events that may occur to a participant during a study:

- (1) Death, or a life-threatening event,
- (2) Hospitalization or prolongation of hospitalization,
- (3) Persistent or significant disability or incapacity,
- (4) Birth defect or congenital malformation,
- (5) Represents, in the PI's judgment, other significant hazards, or potentially serious harm to research participants or others, or
- (6) Any other event as defined in the research protocol.

Investigator Reporting Requirements

Investigators must report SAEs to the IRB within 48 hours of discovery, and 24 hours for deaths and unanticipated problems. For studies that have been determined by the IRB to be greater than minimal risk, these reports should be filed regardless of whether the event appears to be study related or is anticipated. For minimal risk studies, investigators must report only SAEs and unanticipated problems that they believe are possibly, probably, or definitely study-related. It is the IRB's responsibility (not the investigator's) to determine which studies are classified as minimal risk.

Investigators should include the following information

when reporting an SAE, or any other incident, experience, or outcome as an unanticipated problem to the IRB (this can be accomplished by completing FRI's SAE form):

- (1) Appropriate identifying information for the research protocol;
- (2) A detailed description of the adverse event, incident, experience, or outcome;
- (3) An explanation of the basis for determining that the event represents an unanticipated problem; and
- (4) A description of any changes to the protocol or other corrective actions that have been taken or are proposed.

Follow up reports and a final written report should be sent to the IRB as soon as the investigator receives additional information regarding the event.

Reporting Requirements to Institutional Officials and External Agencies

In accordance with 45 CFR 46.103(a) and 46.103(b)(5), the IRB Administrator will ensure prompt reporting of the following to the IRB Chairman and FRI's President and Medical Director:

- (1) Any unanticipated problems involving risks to participants or others,
- (2) Any serious or continuing noncompliance with the Federal regulations for the protection of human subjects, or the requirements, and determinations of the IRB, and
- (3) Any suspension or termination of IRB approval.

The President will contact the Chairman of FRI's Board of Directors and they will decide whether to notify all Board members prior to the next scheduled meeting. In addition, the President will report the three aforementioned events to the supporting agency head (or designee), and OHRP within one month of the IRB's receipt of the report of the problem from the investigator.

The IRB Chairman may decide to call a special IRB meeting to review the unanticipated problem and determine whether to modify the protocol and/or the consent form, suspend the study, or take other appropriate action.

IRB Review of SAEs/Unanticipated Problems

At each convened meeting, the IRB reviews all new SAE/unanticipated problem reports and the corresponding reviewer reports. If protocol or consent form changes have been recommended by either the

Continued on page 5

investigator or the reviewer, the IRB will make the decision to accept/reject these proposed changes or to require new ones. The IRB may require more frequent review to monitor the protocol. In rare instances it may become obvious to the Chairman and the IRB that a study carries an unacceptable, unanticipated risk, and the investigator may be asked voluntarily to suspend the study, if he or she has not already done so, pending its re-evaluation.

The following is a list of examples of corrective actions or substantive changes that might need to be considered in response to an unanticipated problem:

- (1) Changes to the research protocol;
- (2) Modification of inclusion or exclusion criteria to mitigate the newly identified risks;
- (3) Implementation of additional procedures for monitoring subjects;
- (4) Suspension of enrollment of new subjects;
- (5) Suspension of research procedures in currently enrolled subjects;
- (6) Modification of informed consent documents to include a description of newly recognized risks;
- (7) Provision of additional information about newly recognized risks to previously enrolled subjects;
- (8) Suspension or termination of the study.

When reviewing a report of an unanticipated problem, the IRB will consider whether the affected research protocol still satisfies the requirements for IRB approval under HHS regulations at 45 CFR 46.111. In particular, the IRB will consider whether risks to subjects are still minimized and reasonable in relation to the anticipated benefits, if any, to the subjects and the importance of the knowledge that may reasonably be expected to result.

Additional Adverse Event Reporting Requirements

Investigators are also responsible for reporting the following to the IRB in a timely fashion:

- New information that may impact the risk/benefit ratio of a study;
- Irregularities in conducting the study;
- Data and Safety Monitoring Board reports; and
- Copies of external SAEs.

Employees' Corner

Important Announcements!

Employees of Epoch Counseling Center are not eligible to participate in FRI's 401(k) plan through John Hancock. However, FRI does have a 403(b) plan through VALIC that Epoch employees are eligible to participate in. All other employees of FRI are eligible to participate in either the 401(k) plan or the 403(b) plan. Please direct all retirement plan inquiries to **Michele Hipsley**, Director of Administration. Michele can be reached at 410-823-5116 or mhipsley@friendsresearch.org.

Effective January 1, 2007, retirement plan contribution limits have increased to \$15,500 (\$20,500 for employees age 50 and over).

Effective May 21, 2007, **Michele Hipsley** will be filling in for **Norma McCormack** regarding HR services while Norma is out on FMLA. Norma will resume her duties on June 18, 2007. Please direct all HR related issues during this time period directly to Michele.

Effective June 18, 2007, **Norma McCormack** will be filling in for **Julie Edelson** regarding IRB services while Julie is out on FMLA. Julie will resume her duties in late September. Please send all IRB related information during this time period directly to Norma. Norma can be reached at 410-823-5116 or nmccormack@friendsresearch.org.

Effective February 1, 2007, FRI's mileage reimbursement rate increased to 48.5 cents per mile.

Please remember to inform the Payroll and HR Departments of any change to personal information such as home address, telephone number, marital status, education level, etc. This information should be conveyed in writing.

If Principal Investigators would like to receive their monthly statement by email and have not yet informed FRI, please contact **Wanda Cross**, Financial Administrator, at 410-823-5116 or wcross@friendsresearch.org.

Since 2001, Safe House Continues to Make a Difference in its Community



Safe House offers 30–60 day emergency shelter, 6–12 month transitional housing and 13 permanent housing units as well as support services to homeless persons living with HIV/AIDS, who are either living on a low income or no income, and who also suffer from mental illness and/or substance misuse. Safe House's philosophy is high tolerance (Harm Reduction); leaving judgment outside the door. Having a safe place to stay is its first priority. Safe House also offers treatment options when the client is ready.

Safe House has been in operation since February 2001, when its first 16 residents moved into their own apartments in North Hollywood, California. Currently the number of clients at Safe House has grown to 25.

Since operation, Safe House has assisted 447 persons in emergency/transitional/permanent housing. This includes assisting in medical needs (medication management), long term housing (additional housing), resume writing, job search, and money management. All clients are referred to Safe House by an AIDS service provider or Medical/Drug Treatment facility.

The experience at Safe House shows that all persons from all types of backgrounds will be affected by homelessness; HIV/AIDS and substance misuse/mental illness. Each client has his/her own story; unique in his/her own way, but one thing is very clear; HIV/AIDS, substance misuse and mental illness affect all kinds of people.

Safe House was initially funded in 1997 through a grant from the Los Angeles Housing Department, Housing Opportunities for Persons with AIDS (HOPWA) for the amount of \$2,263,910. At that time, approximately \$1,500,000 was used for acquisition and capital improvements for the project, and \$763,910 was expended for operating expenses during the period of April 1997 through March 2003.

In April 2003, Safe House received additional funding through HOPWA in the amount of \$132,707. In February 2003, once again, Safe House received an award of \$50,000 from Emergency Housing Assistance Program (EHAP) and monies from Emergency Food and Shelter Program (EFSP) toward operational costs.

Since 2003 Safe House has continued to receive outside funding from various public foundations such as Morrison Foerster Foundation; Union Bank of California, and the Norris Foundation.

FRI is very proud of the services that Safe House provides to help enrich the lives of those affected by homelessness, HIV/AIDS, and substance misuse, and/or mental illness, and the work that it is doing to better the community overall.

Happy Anniversary!

*Congratulations to the following employees who have recently celebrated an anniversary with FRI.
We appreciate your loyalty and dedication to the organization.*

NOVEMBER	YEARS	DECEMBER	YEARS	JANUARY	YEARS
David Hoyte	10	Thomas Hanlon, Ph.D.	47	Jan Marshall	21
Michael Gordon, D.P.A.	7	Patrick Bogan	38	Dorothea Collins, Sc.D.	9
Stuart King	6	Donnette Randolph	11	Robert Schwartz, M.D.	7
David Highfield, Ph.D.	5	John Roll, Ph.D.	7	Elizabeth Katz, Ph.D.	7
Michele Ricketts	5	Luna Yojay, Ph.D.	6	Julia-Anna Kavich	3
Patrick Tionson	1	Elena Nieves	6	Kimberly Alford	2
				Terrance Hudson	2
				Karin Aebersold	1

FEBRUARY	YEARS	MARCH	YEARS	APRIL	YEARS
Judith Horst	17	Steven Carswell, Ph.D.	10	Diana Caldwell	18
Claudia Reynolds	9	Donna Lucker	9	Monique Wilson, Dr.PH.	11
Ruslan Damadzic, M.D.	8	Ned Rubin	7	Scott Kehir	6
Donnie Watson, Ph.D.	6	Susan Tangires	7	Warren Lee	5
Ma Anna Teresa Mapa	5	Julie Edelson	5	John Hargrave	2
Raymond Szczepanski	5	Sylvia Lyons	2	Veronica Buser	1
		Eric Stahl	1		
		Jennifer Rueschlin	1		
		Jan Gryczynski	1		

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