Summer 2007

GATHERING FRIENDS

THE NEWSLETTER OF FRIENDS RESEARCH INSTITUTE

PI PROFILE: *Cathy J. Reback, Ph.D.*

Cathy J. Reback received her Ph.D. in Sociology from the University of California, Santa Cruz in 1986. Dr. Reback is both a researcher and community provider. In addition to her work as a Research Sociologist and Principal Investigator with Friends Research Institute, she is an Associate Research Sociologist with UCLA Integrated Substance Abuse Programs (UCLA ISAP) and a Core Scientist with the UCLA Center for HIV Identification, Prevention and Treatment Services (UCLA CHIPTS). Additionally, in 1994, Dr. Reback founded the Prevention Division of the Van Ness Recovery House, which provides HIV and substance abuse prevention programs to out-of-treatment substance users, and continues to serve as its Director. In 1988, Dr. Reback began to blend her research to focus on the intersection of HIV risk behaviors, substance use, sexual identity, and gender identity among two marginalized and extremely vulnerable populations: MSM (men who have sex with men) substance users and male-to-female (MTF) transgender women.

Dr. Reback began working in the field of HIV in the early 1980s while a graduate student. Dr. Reback was one of the first researchers in the country to link the rise in HIV infection among MSM to sexual risk behaviors while using methamphetamine. She is the author of the seminal study of gay and bisexual chronic methamphetamine abusers, *The Social Construction of a Gay Drug: Methamphetamine Use among Gay and Bisexual Males in Los Angeles* (available for download at www.uclaisap.org). This work provided the foundation for building a comprehensive continuum of culturally consonant research and service programs for MSM methamphetamine and other substance users. Dr. Reback has an extensive background in conducting community-research collaborations, evaluating behavioral treatment therapies, designing and implementing street-based intervention

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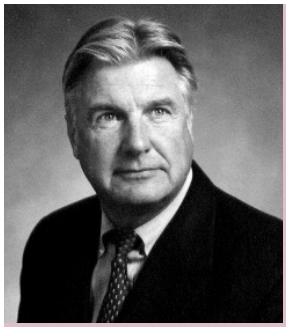
programs for out-of-treatment substance users, and managing large-scale HIV prevention and intervention programs. Additionally, Dr. Reback collaborates with local community-based organizations to adopt, tailor, and transfer evidenced-based interventions into public health and community settings. Dr. Reback has collaborated with ***Dr. Steve Shoptaw*** for over 12 years on major research intervention studies that evaluated behavioral therapies and HIV risk reduction for gay and bisexual male methamphetamine users. Their treatment intervention for MSM methamphetamine users, *Getting Off: A Behavioral Treatment Intervention for Gay and Bisexual Male Methamphetamine Users* (available for download at www.uclaisap.org), has been adopted by researchers and service providers nationally and is currently used in treatment settings, STD clinics and other public health arenas.

Currently, Dr. Reback is Principal Investigator on the following studies: The Universitywide AIDS Research Programs-funded study, *Methamphetamine Abuse Treatment in HIV Prevention: Friends La Brea*, which adopted, tailored and transferred the evidenced-based, gay-specific cognitive behavioral therapy intervention, *Getting Off: A Behavioral Treatment Intervention for Gay and Bisexual Male Methamphetamine Users* from a research setting to a community-based HIV prevention setting, coupling it with a contingency management intervention to create one behavioral intervention for producing sustained HIV sexual and drug risk reductions. More information regarding this study is available at www.friendslabrea.org. The CDC-funded study, *Reducing Methamphetamine Use and HIV Sex-risk Behaviors in Out-of-Treatment MSM: Project Tech Support*, will enroll out-of-treatment, methamphetamine-using MSM into an information technology (IT) communication intervention. Over the course of two weeks, participants engage in a variety of communication technologies (e.g., text messaging, emails, instant messaging) and receive real-time HIV prevention messages, social support and referrals for healthier, prosocial choices regarding drug- and sexual-risk behaviors. The NIDA-funded study, *Voucher-based Incentives in a Prevention Setting (VIPS)*, is a randomized controlled trial that assigns non-treatment seeking gay, bisexual or MSM substance users to either voucher-based incentive therapy or control groups. The study will assess the efficacy of the voucher-based intervention for increasing prosocial and healthy behavior and reducing substance abuse among these non-treatment seeking substance users. Additionally, Dr. Reback currently serves as the Principal Investigator/Director of five county-funded health education/risk reduction programs for gay, bisexual and MSM substance users and high-risk transgender women.

Dr. Reback served as Principal Investigator on the recently completed research-community collaboration to evaluate an evidence-based HIV risk reduction intervention for MTF transgenders, *An Enhanced HIV Intervention for MTF Transgenders (UARP)*; a qualitative study to investigate a potential HIV "bridge" population, *Heterosexual Men Who Have Incidental Sex with Men and/or Male-to-Female Transgenders (City of Los Angeles)*; and served as Co-principal Investigator on a community-research epidemiological study to assess health risks among urban male-to-female transgenders, *The Los Angeles Transgender Health Study (UARP)*. Additionally, Dr. Reback served on Co-Principal Investigator, working alongside Dr. Steven Shoptaw (PI), on the following completed studies: *Behavior Therapy for Gay Male Methamphetamine Abusers (NIDA)*, a randomized control trial to evaluate behavioral and cognitive behavioral therapies for methamphetamine abuse/dependence among gay and bisexual men and to the impact of drug treatment on changing HIV-related sexual and drug use behaviors; *Behavioral Therapies for Gay Male Stimulant Abusers (CSAT)* a randomized control trial that evaluated two behavioral therapies for stimulant dependence among gay and bisexual men and to the impact of culturally-specific drug treatment for gay and bisexual stimulant abusers.

Dr. Reback's community and policy work includes current and past membership on numerous local and national HIV/AIDS and substance abuse task forces and advisory committees.

Gathering Friends will now occasionally feature this new section which will profile FRI Investigators, as a way to familiarize our readers with each Investigator's work and talents. If you are interested in being profiled in an upcoming edition, please contact ***Julie Simon Edelson***, Editor, at jedelson@friendsresearch.org, or at 410-823-5116.



A Message from the President

I am pleased to announce that we are in the final stages of redesigning the FRI website. The basis for the new website is to give it a fresh look but more importantly to emphasize FRI's primary mission, research.

New sections incorporated into the website will include publications, research areas, and Principal Investigators as well as Board of Directors' profiles, to name a few. The new website will contain richer and more comprehensive information and will be easier to navigate for individuals interested in finding out more about FRI, its research, and its Principal Investigators.

I commend the Website Committee for their many hours of research, planning, and creativity in producing the new website. Their team approach and team spirit is clearly demonstrated in how the new website is laid out.

I encourage Principal Investigators as well as research and counseling staff to participate in providing updated information, recent publications, and noteworthy accomplishments for the website in order to keep it current and useful. I look forward to hearing your feedback when the website is launched this fall.

—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.

5/2/07	***Adrienne Ruhf***, Research Assistant at Social Research Center	7/9/07	***Janet Bond***, Research Nurse at Integrated Substance Abuse Program, South
5/7/07	***Pamela Brown***, Research Interviewer at Social Research Center	7/9/07	***Deborah Miller***, Evening Secretary at Epoch Counseling Center, Lansdowne
5/14/07	***Ashley Meyers***, Intensive Outpatient Counselor at Epoch Counseling Center, Essex	7/25/07	***Shenelle Brown***, Data Assistant at Social Research Center
7/2/07	***Amit Levi***, Research Assistant at La Brea Clinic		

Congratulations!

Michael S. Gordon, D.P.A., Research Scientist with SRC since November of 1999, was the recipient of a 2007 Early Career Investigator Award from The College on Problems of Drug Dependence (CPDD). As a recipient of this award, Dr. Gordon received a competitive travel fellowship to attend the 2007 Annual Meeting of CPDD, including registration and travel expenses. Congratulations to Dr. Gordon on this accomplishment.

Ask The IRB Staff

What are the significant differences in FDA and HHS regulations for the protection of human subjects?

The following are the significant differences in FDA and HHS regulations for the protection of human subjects:

- FDA definitions are included for terms specific to the type of research covered by the FDA regulations. A definition for emergency use is provided in the FDA regulations.
- FDA provides exemption from the prospective IRB review requirements for "emergency use" of test article in specific situations.
- FDA provides for sponsors to request a waiver of IRB review requirements (but not informed consent requirements). HHS exempts certain categories of research and provides for a Secretarial waiver.
- Unlike HHS, FDA does not provide that an IRB may waive the requirement for signed consent when the principal risk is a breach of confidentiality because FDA does not regulate studies which would fall into that category of research.
- The FDA list of investigations eligible for expedited review does not include the studies described in category 9 ("Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified") of the HHS list because these types of studies are not regulated by FDA.
- FDA does not discuss administrative matters dealing with grants and contracts.
- FDA has neither an assurance mechanism nor files of IRB membership; therefore, FDA does not require the IRB/institution to report changes in membership.
- FDA may refuse to consider a study in support of a research or marketing permit if the IRB or the institution refuses to allow FDA to inspect IRB records.
- FDA regulations provide sanctions for non-compliance with regulations.
- FDA, but not HHS, provides for an exception from the informed consent requirements in emergency situations.
- HHS provides for waiving or altering elements of informed consent under certain conditions. FDA has no such provision because the types of studies which would qualify for such waivers are either not regulated by FDA or are covered by the emergency treatment provisions.
- FDA explicitly requires that subjects be informed that FDA may inspect the records of the study because FDA may occasionally examine a subject's medical records when they pertain to the study.
- FDA explicitly requires that consent forms be dated as well as signed by the subject or legally authorized representative.

Employees' Corner

FRI Email Accounts

Regarding FRI email accounts ending with friendsresearch.org, our email provider (Techspace) recently updated its servers, which has caused the login screen as well as the layout of the web-based email interface to change. Instead of seeing IMail, you will now see "IPSWITCH web messaging." Please note that the email should work the same as the old email system. If you have any questions or concerns, please contact ***Michele Hipsley*** at 410-823-5116 or mhipsley@friendsresearch.org.

EAP

FRI would like to remind all employees about its Employee Assistance Program (EAP). FRI utilizes APS Healthcare System, which offers counseling, referrals, and interventions for a variety of personal and work related problems that impact the lives of employees.

All contacts with the EAP are strictly confidential and are available to East and West Coast employees and their immediate family members at FRI's expense. You can talk to a professional by phone or make an appointment for a face-to-face consultation.
The phone number for APS Healthcare System is 1-800-999-1077 and its website is www.apshelplink.com. Please call the HR Department, if you would like additional information.

FRI Researchers Awarded with Loan Repayments for their Doctoral Programs

Dr. Steven Carswell

Dr. Michael Gordon

Drs. Steven Carswell and ***Michael Gordon***, two of Social Research Center's newest doctorates, have received awards from the National Institutes of Health's (NIH) Loan Repayment Programs. In exchange for two-year commitments to research careers with FRI, NIH will repay up to $35,000 per year of Dr. Carswell's and Dr. Gordon's qualified repayable educational debt, pay an additional 39% of the repayments to cover their Federal taxes, and may reimburse state taxes that result from these payments.

Dr. Carswell's award is funded through NIH's Health Disparities Research Loan Repayment Program, and Dr. Gordon's through NIH's Clinical Research Loan Repayment Program. The purpose of these repayment programs is to attract health professionals to careers in health disparities research and clinical research, respectively.

To qualify for the Loan Repayment Programs, each candidate must be a U.S. citizen and have a doctoral degree from an accredited institution. In addition, s/he must conduct health disparities or clinical research funded by a domestic nonprofit or U.S. Government entity.

In evaluating the applications, peer review groups comprised of non-NIH scientists are asked to consider the following criteria:

- Appropriateness of the applicant's previous training and experience as preparation for a career in health disparities/clinical research;
- Suitability of the applicant's proposed clinical research activities in the two-year period to foster a career in health disparities/clinical research;
- Assessment of the applicant's commitment to a research career as reflected by a personal statement of long-term career goals and the plan outlined to achieve those goals;
- Strength of recommendations attesting to the applicant's potential for a health disparities/clinical research career;
- Availability of appropriate scientific colleagues to achieve and/or enhance the applicant's research independence; and
- Quality and appropriateness of institutional resources and facilities.

FRI would like to congratulate Drs. Carswell and Gordon for receiving these awards through NIH's Loan Repayment Programs; not only is this a great honor for both of them, but these awards will help pay for their doctoral educations.

A Dialogue of Research and Treatment Information

As noted in the last edition of *Gathering Friends*, 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.

To help facilitate this objective, FRI sponsored *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, gave presentations on their current research endeavors and areas of expertise.

Dr. Reback's presentation focused on integrating substance abuse prevention/treatment and HIV risk reduction for out-of-treatment and treatment seeking gay and bisexual methamphetamine users. She noted that methamphetamine use is significantly associated with HIV infection among gay and bisexual men who use the drug to initiate and enhance sexual encounters. Studies consistently demonstrate that methamphetamine-using gay and bisexual men report an increased number of sexual partners, decreased use of condoms, engaging in unprotected intercourse with non-primary partners, and an increased likelihood of being HIV infected or having a sexually transmitted infection. Therefore, a comprehensive approach for working with both out-of-treatment and treatment seeking gay and bisexual methamphetamine users must address HIV sexual risk behaviors. Dr. Reback discussed a continuum of culturally tailored interventions, from harm reduction to outpatient treatment, for working with this high-risk population.

Dr. Schwartz's presentation focused on new approaches to the treatment of heroin addiction. He noted that buprenorphine, a partial opioid agonist, is revolutionizing the treatment of heroin addiction in the United States. Long acting injectable naltrexone, an opioid antagonist, has recently been approved for the treatment of alcohol dependence and is likely to gain approval for the treatment of heroin addiction as well. This presentation reviewed the effectiveness and use of these pharmacotherapies.

Dr. Katz spoke about role induction as a brief strategy for engaging substance dependent patients into treatment. Dr. Katz's presentation included an overview of the key elements, the theoretical foundation, and important considerations for counselors considering using role induction with substance dependent clients.

The symposium served as the first step of an exchange of ideas between East and West Coast Investigators, and helped familiarize the East Coast Staff with the various research accomplishments that are taking place throughout FRI. In the fall of this year, a similar symposium will be organized on the West Coast to showcase several other of FRI's talented and hard-working Investigators.

Happy Anniversary!

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

MAY	YEARS
Geraldine Hockett	19
Norma McCormack	18
Meredith Portnoff	10
Tassos Kyriakides, Ph.D.	8
Jane Gannod	6
Kathryn Couvillion	6
Melissa Harris	6
Keisha Benjamin	5
Jennifer Knoerlein	2
Arturo Garcia	2
Michael K. Gordon	1
Jimmie Alston	1
Pecolia Silver	1
Deidre Everist	1

JUNE	YEARS
Wanda Cross	43
Amber Hollingsworth	8
James Peck, M.D.	1
Yvonne Keys	1
George Knipp	1

JULY	YEARS
Ronald Maith	16
Cathy Reback, Ph.D.	10
Shakeeta Smith	6
Maureen Keating	5
Peter Theodore, Ph.D.	2
Francine Barker	2
Sarah Wood	1
Shannon Mitchell, Ph.D.	1
Mary DeNardo	1
David Potter	1
Miranda Beck	1

AUGUST	YEARS
Dale Boyd	17
Phyllis Dawes	13
Emily Sears	12
Carolyn Roeth	11
Al Mauerhan	8
Sharon Kelly	7
Bernard Fowlkes	6
Pamela Reid	2
Lakisha Clifton	2
Jennifer Raines	2
Sabrina Cox	2
Sheree Roles	1

Gathering Friends *is a publication of Friends Research Institute, Inc. (FRI).*
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