

F G A T H E R I N G F R I E N D S

FRI THE NEWSLETTER OF FRIENDS RESEARCH INSTITUTE

EPOCH COUNSELING CENTER

Welcomes a New Director



Deborah J. Crocetti, MS, LMFT

Epoch Counseling Center is delighted to welcome Deborah Crocetti as its new Director. Ms. Crocetti was chosen among all of the applicants because of her excellent qualifications and vast experience in substance abuse counseling and program administration. Among other responsibilities, Ms. Crocetti will be responsible for the administrative and fiscal management of Epoch Counseling Center, as well as the clinical supervision of all staff.

Ms. Crocetti comes to FRI from Palm Beach County, Florida, where she was the Outpatient Program Director and Drug Court Program liaison for a tri-county area. In addition, Ms. Crocetti conducted a private practice offering treatment for a variety of issues including substance abuse, eating disorders, adolescent adjustment, marriage and divorce, and psychiatric disorders. Ms. Crocetti has been a licensed Marriage and Family Therapist since 1998. She also has experience working as an individual and group counselor in a residential treatment facility in Delray Beach,

Florida where she became the Director of a program exclusively for women. She later managed a program at Family Service Agency, Inc. in Coral Springs, Florida, where she worked extensively with male batterers and victims of domestic abuse, and was instrumental in facilitating the agency's healthcare accreditations with Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and Council on Accreditation (COA).

Ms. Crocetti is also a certified crisis responder and worked with the crash victims of the Egypt Airlines Crash in Rhode Island in 1999 and has recently assisted in disaster response for Hurricanes Frances and Jeanne in Palm Beach County last September.

Ms. Crocetti received a Bachelor of Arts degree in Sociology from Lee College in Tennessee, and a Master of Science in Marriage and Family Therapy from Nova Southeastern University in Florida. She has also completed her course work for her Ph.D., at Nova, and the completion of her dissertation is pending.

FRI and Epoch Counseling Center are happy to welcome Deborah Crocetti and are anticipating that she will provide a successful and motivating leadership for the program.

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Congratulations!

FRI Research Scientist Honored with a Young Alumni Award

FRI would like to congratulate *Heather Schacht Reisinger* for being honored with the Young Alumni Award from her alma mater, Luther College in Decorah, Iowa. The Young Alumni Award recognizes outstanding achievement of Luther alumni in their vocation or avocation who have graduated in the last ten years. The criteria for this award include early significant professional achievement, demonstrated leadership abilities, and distinctive service to Luther or society-at-large.

Dr. Reisinger received her doctorate in Anthropology from American University last May. Shortly thereafter she began a post-doc at Hopkins and is leading the qualitative research component of FRI's Dr. Robert Schwartz's Treatment Entry and Engagement grant. Dr. Reisinger has published significantly with FRI Principal Investigator, Dr. Mike Agar, as well as on her own.



Institutional Review Board (IRB) Certification

FRI is happy to announce that *Julie Simon Agetstein*, Human Protections Coordinator, has passed the certification examination for the designation of Certified IRB Professional (CIP). This accomplishment is well respected in the research community because it reflects a high level of knowledge in the area of Human Subjects Protections.

Sponsored by Public Responsibility in Medicine and Research (PRIM&R) and Applied Research Ethics National Association (ARENA), the certification examination evaluates and validates individuals' knowledge of ethical principles, historical events, regulatory requirements, and operational and functional issues relating to IRBs and human subject protection programs. The intent of the certification process is to advance the quality of human subject protection programs through the development and education of those assigned responsibility for the day-to-day application of ethical principles, scientific methods, government regulations, and other policies regarding human subject protection.

Congratulations to Ms. Agetstein for receiving this designation of Certified IRB Professional.

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

What is FRI's Serious Adverse Event Reporting Policy?



The purpose of FRI's Serious Adverse Event (SAE) Reporting Policy is to ensure the protection of research participants and to comply with relevant federal regulations.

A Serious Adverse Event (SAE) includes:

- death, or a life-threatening event
- hospitalization or prolongation of hospitalization
- persistent or significant disability or incapacity
- birth defect or congenital malformation, or
- represents, in the PI's judgment, other significant hazards, or potentially serious harm to research participants or others

Principal Investigators (PIs) must report SAEs to the IRB within 48 hours (within 24 hours for deaths). For minimal risk studies, PIs must report only SAEs that they believe are probably or definitely study-related. It is the IRB's responsibility (not the PI's) to determine which studies are "minimal risk." For greater than minimal risk studies, PIs must report all SAEs, regardless of study relatedness.

As noted on the SAE form, the PI must also recommend to the IRB whether the SAE necessitates a change in the study protocol, and/or the consent form. The IRB will make the decision to accept/reject these proposed changes or to require new ones. PIs should use their best judgment in terms of what would best protect and inform study participants.

PIs must also report the following to the IRB:

- new information that may impact the risk/benefit ratio of a study
- irregularities in conducting the study
- Data and Safety Monitoring Board reports

FRI's Medical Director will review each SAE report. In the case where the Medical Director is involved in the study, the SAE will be reviewed by an external reviewer.

If PIs do not comply with this policy, they may be required to attend additional IRB-approved training, or participate in other corrective actions as determined by the IRB. If the failure to report is considered egregious, the study may be suspended and/or its approval revoked.

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

- any unanticipated problems involving risks to participants or others
- any serious or continuing noncompliance with the Federal regulations (45 CFR 46) for the protection of human subjects, or the requirements and determinations of the IRB
- any suspension or termination of IRB approval

The Executive Director will report the three aforementioned events and all deaths that have been determined to be possibly, probably, or definitely study related to FRI's Board of Directors, OHRP, and FDA (if appropriate).

Notice to PIs:

We ask that all Principal Investigators notify FRI of any changes to contact information, especially email addresses, to ensure that they receive their monthly expenditure reports as well as other correspondence from FRI. If a Principal Investigator/Project Manager would like to receive their monthly report by email as opposed to regular mail, please inform Wanda Cross, Financial Administrator, at wcross@friendsresearch.org.

Social Research Center Staff Satisfaction Survey

In addition to its primary focus of identifying and designing prevention and intervention programs for the Baltimore community, Social Research Center (SRC) has taken recent strides intended to bolster the workings of its own in-house employee community. At the end of 2004, SRC established the Staff Development Committee to strengthen various key areas of concern such as career development, mentorship, and staff morale. After the initial brainstorming session, members of the Committee determined that a staff satisfaction survey might assist in assessing employees' impressions of their workplace environment. Prior to the implementation of the survey, preliminary research was performed to gather ideas from similar surveys with respect to content, style, and reliability. Special attention was given to developing an instrument that would address the Committee's major areas of concern while also discovering employees' varying opinions regarding their roles at SRC.

A 31-item satisfaction survey was designed to provide usable data to the Committee and employees at SRC. Twenty-five of the items addressed such issues as perceptions of staff and individual morale, satisfaction with job duties and opportunities, fringe benefits, and workplace dynamics. A five-point scale was used, whereby one represented the lowest level of satisfaction and five represented the highest. The remaining questions were open-ended, affording staff members the opportunity to express themselves regarding things they liked best about SRC, things they would change, and their overall impressions of the Center. Concerns regarding confidentiality and anonymity were addressed through the use of a computer-assisted survey software program and the lack of collecting any identifiable information. Employees were able to complete the survey at a private computer station and their responses were saved directly in a separate database file.

Thirty-five employees participated in the survey. An analysis of the data yielded mostly positive impressions of SRC. For example, the staff was most pleased with the level of flexibility they were given to perform their jobs, and the relationships with their supervisors. The average scores for these items were 4.80 and 4.65, respectively. Employees also indicated that they had a good working knowledge of the type of work performed at SRC. Although the average scores were still slightly favorable, staff members were less pleased with the opportunities for advancement (including knowledge about other available positions within the organization) (3.63), and the health benefits currently being offered by the Center (3.22). Sixteen of the respondents indicated that the best thing about working at SRC was the flexible work schedule and the independent working environment. Seven people noted that they would like to improve communications between Human Resources, senior management, and assistant staff across all levels within FRI. Overall, staff members were generally pleased with the environment at the Center and they were pleased with the Center's interest in making improvements. An overwhelming majority (91%) of the employees rated the SRC as either a good or excellent place to work, and a large number (85.7%) would recommend the Center to a friend looking for employment.

As a first effort, the staff satisfaction survey provided the Committee with beneficial information regarding the survey process, the computer-based survey method, and most importantly insight into the feelings, desires, and concerns of staff members. As such, the results provide the Committee with ideas about potential next steps and specific areas to target in terms of staff development. As a final point, the Committee has gathered some valuable information regarding employee morale at SRC and, through the use of this survey, has demonstrated to staff its willingness to incorporate employees in the process of improvement and development at SRC.

—Jason M. Callaman, M.S.



A Message from the Executive Director

I am pleased to announce that FRI will embark upon a new marketing effort this year, in hopes of acquiring new business opportunities and recruiting additional high-quality

researchers. One facet of this marketing endeavor is to increase FRI's exposure and inform potential clients of our fifty years of grants management and world-class research by attending research related conferences over the next 12 months as an exhibitor. Our new Conference Booth, complete with new brochures and handouts, will be manned by Ms. Norma McCormack, Human Resources Manager and Human Research Protections Supervisor, Mr. Ned Rubin, Director of Quality Improvement, and myself. We will be attending the American Society of Addiction Medicine's Dallas meeting in mid-April, the Society for Prevention Research's Annual Meeting in Washington, D.C. in May, and the College on Problems in Drug Dependence's Annual Meeting in Orlando in June. As an exhibitor, we hope to speak with new researchers and seasoned investigators who may be weary of academic politics and excessive overhead rates, and let them know that FRI can effectively and efficiently manage the administrative and fiscal aspects of their grants and also provide them with a strong human subjects research protections program, including IRB services.

FRI would appreciate your help as well. If you know of a young investigator just embarking on his or her career,

or perhaps an experienced researcher wanting to leave the large institutional setting, please give me a call at 1-800-822-3677. I will be happy to contact them directly and send them information regarding FRI and what we can do for them. Furthermore, if you have a suggestion concerning any additional conferences or sites where we can appear with our new Conference Booth, please email Ned Rubin at nrubin@friendsresearch.org.

As Executive Director of FRI, I am excited about this new marketing initiative, and optimistic that we will begin to embark upon new growth opportunities, while continuing to nurture our talent to provide the thoroughly professional and personalized service that FRI has come to represent.

Patrick F. Bogan

Employees' Corner

FRI would like to inform its employees of the following changes:

- FRI's 401(k) plan has changed its name from Manulife to John Hancock. Manulife Financial Corporation acquired John Hancock Financial Services, Inc. and adopted the John Hancock brand, making the name change effective January 1, 2005. Nothing has changed in the 401(k) account except that the employees' on-line access has a new web address.

To access your 401(k) account use this address:

www.jhancockpensions.com. You will be asked to put in the contract number which is: 17488

If you do not presently belong to the 401(k) plan offered through Friends Research Institute, Inc. and wish to have pre-tax payroll deductions put into this savings plan, you may contact LeAnne Zufall, Payroll Administrator, for an application. She can be reached at 410-823-5116 or lzufall@friendsresearch.org.

- Effective March 1, 2005, the mileage reimbursement rate increased to 40.5 cents.



Important Newsletter Information

Please note that this will be the final mailed edition of *Gathering Friends*. Effective July 2005, a PDF file of *Gathering Friends* will be emailed to all employees and our reader list. Current editions will also be available online at our website, www.friendsresearch.org. If you are not sure if you are on our email list and would like to receive quarterly editions of *Gathering Friends* in your inbox, please email Julie Simon Agetstein, Editor, at jagetstein@friendsresearch.org.



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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.*

JANUARY	YEARS	FEBRUARY	YEARS	MARCH	YEARS
Jan Marshall	19	Judith Horst	15	Gail Needer	17
Dorothea Collins, Sc.D.	7	Christopher Hough, Ph.D.	9	Steven Carswell	8
Robert Schwartz, M.D.	5	Claudia Reynolds	7	Donna Lucker	7
Elizabeth Katz, Ph.D.	5	Edward Sanders	6	Leslie Amass, Ph.D.	5
Jeannette Taylor	4	Ruslan Damadzic, M.D.	6	Jonathan Kamien, Ph.D.	5
Pedro Mercado	3	Donnie Watson, Ph.D.	4	Ned Rubin	5
Erin Huber-Smith	1	Ma Anna Terresa Mapa	3	Anna Soisson	5
Suzette Gelacio	1	Raymond Szczepanski	3	Susan Tangires	5
		Karen Dellert	2	Etsegenet Meshesha	3
				Julie Agetstein	3
				Mely Silverio, Ph.D.	1
				Yanling Wei	1