



# CARE CHRONICLES

June 12, 2006

VOLUME 2/ISSUE 4

## Monthly Feature: Good Clinical Practice and Best Financial Practices

Duke CARE strives to provide our patients with the opportunity to participate in innovative clinical research. Following Good Clinical Practice Guidelines, Duke CARE provides optimum staff coverage to meet protocol timelines provided by sponsors. A role of CARE is to ensure that our clinical research subjects are enrolled follow **Good Clinical Practice Guidelines**. For guidance in the protection of human subjects, please refer to the following websites.

<http://ohsr.od.nih.gov/guidelines/nuremberg.html>

The Nuremberg Code of 1947

<http://ohsr.od.nih.gov/guidelines/helsinki.html>

The Helsinki Declaration of 1964

(amendments through Year 2000)

<http://ohsr.od.nih.gov/guidelines/belmont.html>

The 1979 Belmont Report

<http://www.cms.hhs.gov/HIPAAGenInfo/>

HIPAA

<http://www.fda.gov/oc/ohrt/irbs/default.htm>

Guidance for IRBs and Clinical

Investigators

<http://www.fda.gov/oc/ohrt/irbs/faqs.html>

A Guide to Informed Consent, click on

*Informed Consent Process*

<http://ohsr.od.nih.gov/>

Office of Human Subjects Research

<http://www.fda.gov/oc/gcp/regulations.html>

US Food and Drug Administration Good

Clinical Practice Program

<http://irb.mc.duke.edu>

Duke University Health System IRB

**Best financial practices** are of equal importance to ensure that study related expenses are billed to the study sponsor and not to patients and government or third party payers. Financial compliance is a responsibility of the investigator and the study (coordinator) staff.

### Compliance Responsibilities

#### *Principal Investigator*

1. Ensure PI IRB Certification is updated

<http://researchethics.mc.duke.edu/>

2. Ensure PI Research Costing Compliance Training is complete

<http://rcc.compliance.duke.edu/Training/PI/index.html>

3. Ensure Investigator has attended the Clinical Research Lecture: **Good Clinical Practices, Effort Reporting, & Billing**

<http://staff.medicine.duke.edu/modules/eguide/>

4. Ensure annual compliance training is updated as required by the Joint Commission on Accreditation of Hospital Organizations

<http://www.safety.duke.edu/>

#### *CARE Personnel*

1. Ensure all research staff that are listed as key personnel on the IRB protocol have completed/updated IRB certification
2. Ensure key research staff are familiar with the clinical trial billing process for each protocol for which they are responsible
3. Ensure all research staff have updated their annual compliance training as required by the Joint Commission on Accreditation of Hospital Organizations



# CARE CHRONICLES

VOLUME 2/ISSUE 4

## *CARE Personnel*

### **Medical Director**

T.J. Gan, MD  
Assistant, Angela Rogers 681-2470

### **CARE Operations Manager**

Jerry Kirchner 970-2814

### **CARE Financial Analyst**

Lindon Pearson 681-6727

### **Noncardiac Research Operations Manager**

Felicia Anderson 970-3559

### **Cardiac Research Operations Manager**

Roger Hall 970-6617

***In follow up to Duke Employee Appreciation Week, May 20-25, 2006 we again recognize and thank the CARE Clinical Research Staff not listed elsewhere in this Newsletter***

Narai Balajonda, Bob Broomer, Maricel Celerian, Bonnie Funk, Michael Hill, Dorris Lockamy, Catherine Williams, Angela Braswell, Hollie Garner, Chonna Campbell, Blas Catalani III, William Chisenhall, Glenn Davis, Mike Elgasim, Christopher Kigongo, Satarah Latiker, Charles Peters, Yanxia Sun, Peter Waweru, Lakisha Williamson, Sarah Woodring

***Scroll down to the next page***



# CARE CHRONICLES

VOLUME 2/ISSUE 4

*A Message from Zarrin Brooks, Departmental Grant Administrator, regarding a funding opportunity-please forward to staff who may qualify to apply*

**Announcing the reformulation of the Career Awards in the Biomedical Sciences (CABS) to  
Career Awards for Medical Scientists (CAMS)**

**Providing clinically trained individuals with bridging support in basic biomedical, disease oriented, translational, or molecular, genetic, or pharmacological epidemiology research at  
North American degree granting institutions**

**Application Deadline for the 2007 Award Cycle: October 2, 2006**

Dear Colleague:

Enclosed is the [2007 program brochure](http://www.bwfund.org/brochures/2007%20CAMS%20brochure.pdf) (<http://www.bwfund.org/brochures/2007%20CAMS%20brochure.pdf>) describing our [Career Awards for Medical Scientists](http://www.bwfund.org/programs/CAMS/cams_index.html) ([http://www.bwfund.org/programs/CAMS/cams\\_index.html](http://www.bwfund.org/programs/CAMS/cams_index.html)), an award that is the result of the reformulation of the CABS program due to the anticipated impact of NIH's CABS-like K99/R00 award. The five-year \$700,000 award is intended to support the physician scientist (M.D.; M.D., Ph.D.; D.V.M.; D.V.M., Ph.D.; D.D.S.; D.D.S., Ph.D., etc) during the final one or two years of a mentored position and then allow the physician scientist to carry that support to an independent position. It is anticipated that at least 17 awards will be given for the 2007 award cycle.

The CABS program ran for 12 years and provided 241 young scientists with more than \$100 million in support. BWF sees the K99/R00 award as confirmation of the success of the CABS program and the introduction of the new NIH award gives BWF an opportunity to refocus to an area that BWF feels needs nurturing.

Please share this brochure with eligible researchers at your institution. BWF also encourages institutions to nominate their full complement of five candidates. Candidates must be citizens or permanent residents of the United States or Canada.

BWF is an independent private foundation dedicated to advancing the biomedical sciences by supporting research and other scientific and educational activities. We are not affiliated with any corporation. If you have questions, contact Rolly Simpson, acting program officer, at (919) 991-5110 or [rsimpson@bwfund.org](mailto:rsimpson@bwfund.org). Further information and application instructions are available on our Web site at [www.bwfund.org](http://www.bwfund.org).

Sincerely,

Queta Bond



# CARE CHRONICLES

VOLUME 2/ISSUE 4

*IRB Submission Reminders, Updated Research Ethics Home Page & Revised Log-in Procedure to Educational Modules* <http://researchethics.mc.duke.edu/>

- The (IRB) departmental deadlines for June are June 13, June 20 and June 27.
- IRB submissions are due in Suite 3414 DN by 5 P.M. The submission must include 1 original and 3 photocopies. Please ensure that a completed CARE study implementation form is attached to your original submission.

**Please be reminded that the Department will be transitioning to eIRB submissions for new protocol applications and their associated amendments and adverse events.**

The Research Ethics home page has been updated with a new appearance and a new format and the log-in process for the Research Ethics educational modules has been revised. Users are no longer allowed to log-in with their Duke dempo-user names and passwords. Duke NetID and NetID passwords are now necessary to access the Research Ethics educational modules.

Contact the Help Desk at 684-2200 if you need assistance with your Duke NetID, NetID password, or have any questions regarding the use of the NetID.

The link for a personal listing of completed educational modules is conveniently located on both sides of the redesigned site. *My Transcript* link on the left side is listed under the "IRB Requirements" link. On the right side, the link is available under "Quick Links".

For non-Duke researchers listed as key personnel on Duke studies there is a new automatic procedure to access the educational modules. For first time non-Duke users, click on an educational module title link. Simply follow the instructions listed. For a group of non-Duke individuals on a study, please send a list of key personnel to Charlotte Coley at [coley007@mc.duke.edu](mailto:coley007@mc.duke.edu).

## *Congratulations*

- Congratulations to Blas Catalani III, Pre Doctoral Award Runner-up for his abstract **Aprotinin use and allograft function after off-pump bilateral lung transplantation** at the Department of Anesthesiology Fourteenth Annual Academic Evening on May 16, 2006. Blas is a Clinical Trials Assistant with CARE.

## *News*

- **Arrivals and Departures**- CARE welcomes the following new staff: Gamal Saleh, Research Associate, Yuval Patel, Clinical Trials Assistant, and Adam Buntaine, Clinical Trials Assistant.

CARE says goodbye and best wishes to the following staff: Cristina Francois, Clinical Trials Assistant, Christine Strayhorn, Clinical Research Coordinator, and Matt McDaniel, Clinical Research Coordinator.

- If you have information or ideas for the CARE Newsletter, contact Jerry Kirchner.