

Monthly Feature: What services CARE provides on federally funded clinical projects

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.

When applying for a federally funded clinical project there are several roles and responsibilities that the Principal Investigator, Principal Investigator's Assistant and CARE personnel perform throughout the grant application process. Please see below roles for each individual as guidance to ensure applications are submitted timely and accurately.



Grant Application Roles

Principal Investigator

1. Ensure PI Research Costing Compliance Certification is updated
2. Identify personnel, effort, and role on grant
3. Targeted/Planned subject enrollment
4. Patient care tests to be performed
5. Specific Aims and Abstract
6. Research Plan
7. Appendices to be included in application

CARE Personnel

1. Prepare budget using information provided by PI
2. Obtain pricing for all patient care costs, supplies, and salary information on all personnel
3. Prepare facility resource information
4. Enter application into SPS
5. Maintain structure of grant application
6. Print grant application from SPS
7. Prepare table of contents
8. Submit to Office of Research Administration (Grants & Contracts) for review and approval
9. Obtain institutional signatures
10. Deliver signed application to PI's staff assistant

PI's Staff Assistants

1. Ensure Bio-sketches and CVs are updated
2. Attach research plan, any appendices, etc. to application per agency guidelines
3. Prepare photocopies of grant application per agency guidelines
4. Ship via Fed-Ex to federal agency



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VOLUME 2/ISSUE 3

CARE Personnel

Medical Director

T.J. Gan, MD

Assistant, Angela Rogers 681-2470

CARE Operations Manager

Jerry Kirchner 970-2814

Financial Analyst

Lindon Pearson 681-6727

Noncardiac Research Operations Manager

Felicia Anderson 970-3559

Scroll down to next page



CARE CHRONICLES

VOLUME 2/ISSUE 3

A Message from Mollie Sykes, Director, Office of Research Administration (ORA)

NIH recently changed the form packets for **new, competing and non-competing** applications. A summary of the major changes follows. The Administrative Development Group (ADG) technical team at Duke is currently modifying the Sponsored Projects System (SPS) to accommodate the new forms with an expected completion date of May 10. If you have questions or need additional information, please contact Jerry Kirchner or Zarrin Brooks (Department of Anesthesiology Grant Administrator) or ORA at 684-5175 or gemail@mc.duke.edu.

PHS 398 Paper Forms (new and competing): Applicants Preparing Applications for **Submission/receipt Dates On/After May 10, 2006:** Revised forms (dated rev. 4/06) and instructions are available for immediate use and are **required** for paper applications being prepared for submission/receipt dates on/after May 10, 2006. After this date, ***applications submitted using previous versions of form pages that have been updated, may be delayed in the review process.***

PHS 2590 Paper Forms (non-competing): Applications Preparing progress reports for **Submission/receipt Dates On/After June 1, 2006:** Revised forms (dated rev.4/06) and instructions available for immediate use and are **required** for paper applications being prepared for submission/receipt dates on/after June 1, 2006.

If you have submissions that require the revised forms prior to the SPS changes, the paper forms can be downloaded from the NIH website, be sure to use the Revised 04/06 form version.
<http://grants1.nih.gov/grants/forms.htm>

NIH Guide Notice forwarded by Zarrin Brooks, Departmental Grant Administrator

NIH ANNOUNCES PLANS TO ELIMINATE MAILING OF PAPER ASSIGNMENT AND CHANGE OF ASSIGNMENT LETTERS

Notice Number: **NOT-OD-06-066**

Key Dates, Release Date: May 3, 2006

Issued by National Institutes of Health (NIH), (<http://www.nih.gov/>)

The purpose of this Notice is to inform the research community of a change, effective June 1, 2006 in business process concerning assignment and change in assignment notification letters.

In September 2005, NIH announced the elimination of the mailing of Peer Review Outcome Letters and Summary Statements. As the NIH continues towards its goal of a paperless grants process, effective June 1, 2006 NIH will no longer send paper notification of assignment and change of assignment letters.

A major motivation for this change is that effective May 10, 2006 all applications submitted to NIH must include the eRA Commons User name for all Project Directors/Principal Investigators (PD/PIs). This applies to paper applications as well as electronic applications. Therefore, investigators will need to use the eRA Commons, a Web interface where NIH and the applicant organizations are able to conduct extramural research business electronically, to obtain this information. Note: this change in business process does not apply to applications for the Agency for HealthCare Research and Quality or the Centers for Disease Control and Prevention.



CARE CHRONICLES

VOLUME 1/ISSUE 2

IRB Submission Reminders

- The remaining (IRB) departmental deadlines for May are May 16 and May 23, and May 30.
- 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.

June 1, 2006 NIH Grant Application-Reminders for May, 2006

- Monday May 1-Application finalized for ORA (Grants & Contracts) submission (route in SPS)
- Wednesday May 3-Send face page (and signed DPAF) to ORA for institutional signature
- Friday May 12-Pack & Ship
- Monday May 15-Received at NIH

News

- The clinical research staff gathered at the University Club on Friday April 7, 2006 for the 3rd Annual CARE Educational Retreat. We were fortunate to have two wonderful speakers for this year's event. Colleen Denny, Research Fellow in the Department of Clinical Bioethics at the National Institutes of Health presented "Defining and Dealing with "Vulnerability" in Human Subjects Research". Nancy M.P. King, Professor of Social Medicine at the University of North Carolina at Chapel Hill presented "Risks of Harm & Potential Benefits in Research: A Primer". The presentations were followed by a dynamic question and answer session with the speakers. The event also included the presentation of Teamwork Awards to Glenn Davis and Mike Elgasim; congratulations to Glenn and Mike. The educational retreat adjourned following a buffet luncheon.
- CARE welcomes Hollie Garner to the Department of Anesthesiology. Hollie transfers from the Department of Nursing effective April 24, 2006. Hollie is a registered nurse and will hold the position of Clinical Research Coordinator I, coordinating clinical research for Dr. Terri Monk at the Durham VA Medical Center. Welcome Hollie!
- During National Nurses Week (May 6-12), CARE recognizes our nurses, our CARE clinical research (nursing) staff: Angela Braswell, Bonnie Funk, Hollie Garner, Dorris Lockamy, Christine Strayhorn, Elizabeth Perez and Cathy Williams.
- If you have information or ideas for the CARE Newsletter, contact Jerry Kirchner.