

Monthly Feature: Resources Available at Duke to Support Your Clinical Research

Duke CARE strives to provide our patients with the opportunity to participate in innovative clinical research. Following Good Clinical Practice Guidelines and Best Financial Practices, Duke CARE provides optimum staff coverage to meet protocol timelines provided by sponsors. A goal of CARE is to communicate to the Department, resources available at Duke, which can be utilized to facilitate clinical research. In this issue, we provide an overview of the **Clinical Trials Quality Assurance Office** and the **Office of Research Administration** at Duke. These offices have resources readily available to Principal Investigators, Clinical Research Staff and Grant Administrators.

The Clinical Trials Quality Assurance (CTQA) Office is a section of the DUMC School of Medicine Compliance Office with a primary responsibility to verify that the rights and welfare of human subjects are met.



The following information can be found at the CTQA website,

<http://medschool.duke.edu/compliance>

The purpose of CTQA is to verify that: 1) the rights and welfare of human subjects are met; 2) the conduct of the clinical trial is consistent with the approved protocol, including regulatory requirements, that reported study data are accurate, complete and verifiable from the source documents; and 3) to investigate complaints and/or allegations of noncompliance with research regulations or

applicable laws. The staff will also help provide information to faculty and staff on regulatory compliance and Good Clinical Practice (GCP) Guidelines concerning human subjects, data collection and data management.

What can CTQA do?

- 1) Conduct routine, proactive, on-site reviews
- 2) Conduct directive, reactive, “for-cause” reviews
- 3) Assist in preparing sites for external audits
- 4) Provide consultation to research personnel
- 5) Assist principal investigator and study staff in conducting self assessments
- 6) Monitor on-going research activities
- 7) Collaborate with the IRB regarding regulatory issues raised by sponsors or other agencies
- 8) Provide regulatory training and incidence resolution

CTQA has numerous templates and resources located at the website that can be adapted for specific protocol needs. Examples are a sample regulatory document tracking form, a sample delegation of authority list, a sample enrollment log, and a drug/device dispensing log, to name a few. Tools to help staff prepare for internal CTQA reviews or external audits include a review assessment tool, a checklist for preparing for reviews and audits, a regulatory binder template, suggestions for writing standard operating procedures, and a glossary of common clinical trials terminology. There are links to government regulations and professional organizations websites. Templates for reporting outside audits and inspections, draft standard operating procedures for the Duke community are also available, as well as information regarding the CTQA Lunch and Learn sessions and the new (study) coordinator training, with links to previous Lunch and Learn lectures and coordinator training materials used in the one day training sessions. Visit the website soon to determine how you and your study may benefit from the resources.



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The Office of Research Administration (ORA), previously called Grants & Contracts, is responsible for supporting investigators and administrators in the School of Medicine and the School of Nursing by managing externally sponsored research projects through the pre-award process. The following information can be found at the ORA website

<http://research.som.duke.edu/modules/home/index.php?id=1>

ORA staff process approximately 3,000 applications per year for the two schools for federal, commercial, foundation, and specialty society funding. The Office provides training to investigators and administrative staff on pre-award processes and is available to provide customized consultative services to investigators and research administrators. The mission of ORA is to advance extramural research programs and improve the efficiency of the Duke Medical Center research community in procuring and managing research funding. The vision of ORA is to strive to be a model research administration program, with the goal to provide outstanding administrative, informational, systems, and logistical support to the Duke Medical Center research community and to ensure compliance with policies and regulations of the institution, sponsors, and federal oversight agencies.

Institutional resources available to assist in grant development include boilerplate language for grants, generic templates for Letter of Intent (in response to an RFA), letter of support (from consultant, collaborator, etc.), K Grant Template, RO1 Grant Outline, and a Blank Continuation Page for NIH Applications; just as important, "ORA contacts" information for Anesthesiology. Presentations/Slide Sets from the "Grants & Contracts 101 (and 201) for School of Medicine" and "Grant Managers' Meeting" are available, as are lecture materials from the "Professional Development Seminar Series". The schedule for "Sponsored Programs System Training" and "Grants & Contracts Training" is available at the website, in addition to "Institutional Training Grant Resources" and links to "Other Duke Research Resources", such as the IRB, Office of Sponsored Programs, Office of Corporate Research Collaborations and Research Costing & Compliance.

Investigators from various Duke Departments have also generously submitted sample proposals for posting at the website as an available resource for other investigators. Information on Duke Business Practices is linked at the website; finally, numerous announcements are posted at the ORA homepage to ensure researchers have the latest information related to grant submission. Visit the website soon to determine how you may benefit from the resources provided by ORA.

A Message from Nancy Rhodes, Associate Dean for Clinical Research Administration & Vice Chair, Administration, Finance & Business Strategy

The School of Medicine (SoM) Clinical Research Support Office (CRSO) is holding a mandatory clinical research coordinator training session. The objective of this forum is to introduce key research personnel to the new SoM initiative regarding guidelines for clinical research being conducted at Duke University, including the overview of the CRSO and billing compliance. This will also provide the opportunity to network with key research personnel from all departments in the SoM.

Clinical research staff who have not yet attended a training session should plan to register at the link below for lectures scheduled in the coming weeks. Note, the registration link has changed to

<http://crso.som.duke.edu/modules/eguide/>



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Why is this important? Read the story from the Associated Press, forwarded by Duke Research Costing Compliance on July 6, 2006, and published in the July 10th CARE Chronicles Newsletter. You may locate the July CARE Newsletter at <http://dukecare.org>

A Message from Zarrin Brooks, Departmental Grant Administrator

NIH Grant "eSubmission" Classes - Open to Faculty and their Assistants

"JUST-IN-TIME" training: NIH has changed the SF424 forms as well as modified the submission process. Duke is continuously adapting their systems and improving the processes to accommodate these changes.

To provide the most up-to-date information, the Office of Research Administration (ORA) has adopted a "just-in-time" training approach. For each major NIH deadline, ORA will provide new training sessions to ensure faculty and grant managers have the latest changes.

A series of eSubmission classes will be held over the next few weeks and will cover both Grants.Duke and eSNAP. If you have a new or resubmission of a R03, R21, R33 grant due or if you have a non-competing SNAP progress report due for October 1 or November 1, you should take the training. Or, if you are just curious about what is going on and have questions, please join a session.

No registration is required, and all classes will be held in the Hock Plaza Auditorium, 2424 Erwin Road.

Remaining Sessions

Wednesday 9/13 8:30 – 11:30 am or 1:30 – 4:30 pm

Please check the Departmental Newsletter during the coming weeks for additional information or visit the ORA homepage <http://research.som.duke.edu/modules/home/index.php?id=1>

IRB Submission Reminders

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

- Upcoming (IRB) departmental deadlines are September 19 & 26.
- 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. You should be using form version February 3, 2006. If you need the current electronic version, please contact Jerry Kirchner or Angela Rogers. You may also view this version by locating the March 13, 2006 CARE Chronicles Newsletter at <http://dukecare.org>

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

Additional Reminder

Have you registered your consented subject for your "included" (IRB-approved) protocols?

<https://banquo.duhs.duke.edu/crso/registry.nsf/Sub>

Register subjects who consented on therapeutic (or non-therapeutic) research studies which involve clinical procedures, clinical tests or clinical care at a Duke Facility or PDC Clinic and/or studies whereas Duke receives payments from a sponsor (external or internal) or from a 3rd party payor for clinical care, clinical test, or clinical procedures performed at a Duke Facility or PDC clinic.



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News

- CARE says goodbye, thank you and best wishes to Research Associate Li June Tay. June has been with us for the past 6 weeks, assisting in the enrollment of healthy volunteer subjects in the Department's Human Pharmacology Laboratory. She will be returning to Medical School in London.
- CARE welcomes Gladwell Mbochi. Gladwell is a Clinical Trials Assistant and is assigned to work in the NORG Testing Office. Gladwell's primary responsibility is to complete neuropsychological testing and economic and quality of life assessments of cardiac surgery patients participating in NORG studies. Welcome Gladwell! CARE also welcomes Ashley Western. Ashley is a registered nurse who will serve as the General Clinical Research Center (GCRC) scatter nurse assigned to NORG protocols. Ashley's primary responsibility will be to preoperatively screen all cardiac surgery patients to determine eligibility for participation in NORG studies. Welcome Ashley!
- The next Clinical Trials Quality Assurance Lunch & Learn session will occur on September 18; the topic is "Consent with Special Populations and Legally Authorized Representatives", presented by Warren Taylor, M.D. The CTQA Lunch & Learn series is free and open to the public. You may register for the monthly series by E-mailing CTQA@mc.duke.edu. Check the CTQA website for updates: <http://medschool.duke.edu/compliance>. CTQA also offers "New (Study) Coordinator" Training, the next training is scheduled for November 21, 2006.
- The CARE Holiday Luncheon date has been set for Thursday December 14, 2006, beginning at 11:30 a.m. Investigators should be aware that this is one of two dates during the calendar year when the clinical research staff have the option of limiting enrollment, so to allow their attendance at the event. Reminders will be sent to investigators as the date approaches.
- If you have information or ideas for the CARE Newsletter, contact Jerry Kirchner.

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