



# RESearch Coordinators United in Excellence (RESCUE)

## Newsletter

*From the*

December 21, 2007

Meeting and Holiday *Cookie Swap*

### Announcements –

Amy Claus had requested that we make the following announcement in her absence: “In 2008, MCGHI will have price increases for research services” and someone from OCIS will follow up with details later.

### Clinical Trial Registry

Michelle Christiano had an announcement about new requirements for registering a Clinical Trial:

The recently enacted [U.S. Public Law 110-85](#) (also known as H.R. 3580, or Food and Drug Administration Amendments Act of 2007), Title VIII, Section 801 mandates the expansion of ClinicalTrials.gov. Specific implications for the Protocol Registration System (PRS) include:

- Several data elements that were previously optional will become required. Generally these elements were already required by ICMJE/WHO policies.
- A small number of data elements have been added to facilitate full compliance with the new law and to support core ClinicalTrials.gov operations.
- Certain device trials that relate to unapproved or uncleared devices, will not be posted until the device is approved or cleared by the FDA. Note that the requirements for registering such trials (e.g., time of initial registration, required data elements) are not affected by this provision.

The newly required data elements, if left unspecified, are now identified in the PRS with messages of the form:

**⚠WARNING: [Data Element Name] has not been entered.**

**By law, the additional information is required as of December 26, 2007 (90 days after enactment of the law) for certain trials.** Registrants are advised to begin providing the revised set of data elements now for new registrations and active studies. Studies that were completed prior to enactment (September 27, 2007) are not subject to the new registration rules, but may be updated at the discretion of the registrant.

Prior to September 2007, the International Committee of Medical Journal Editors (ICJME) established a requirement that all clinical trials be entered in a public registry before the onset of patient enrollment, as a condition of consideration for publication. Its member journals area available at <http://www.icmje.org/jrnlist.html>

CAUTION: The PRS will not enforce the inclusion of the newly required data elements until September 27, 2008. It is your responsibility to ensure that your registration meets the requirements of applicable laws and regulations. Acceptance by the PRS and assignment of an NCT number to a protocol record does not ensure full compliance with all applicable laws.

Complete information and directions on registering clinical trials are available at <http://www.mcg.edu/research/ohrp/documents/ClinicalTrialRegistryRevised.doc> .

## Top Ten Relaxation Tips for Reducing Holiday **Stress**



1. Create realistic expectations -- don't try to make this the perfect holiday.
2. Learn to say "no" to extra obligations that might stress you out.
3. Take short relaxation breaks to let go of tension.
4. Get involved in a volunteer activity where you help others.

5. Tap into your natural creativity and create a hand-made gift.
6. Eat and drink sensibly, and get plenty of exercise and sleep.
7. Practice being a peacemaker if family squabbles erupt.
8. Balance your spending of time and money to improve your quality of life.
9. Create a new holiday tradition that builds connections among your family and friends.
10. Reflect on the deeper meaning and spirit of the holidays for you personally, for your family, and for humanity and the world.

*Excerpted from the following:* Joel Levey and Michelle Levey are the authors of *The Fine Arts of Relaxation, Concentration, and Meditation* (Wisdom Publications, 2003) and *Living in Balance* (Conari Press, 1999).

**Next Meeting: January 18<sup>th</sup>**

**Topic: "New MCGHI Policy for Study Billing to Insurance"**