



Aureus Research Consultants

The GOLDEN GLOW



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Happy Holidays from Aureus Research Consultants!

Wishing you...
every happiness this Christmas season and
success in the New Year. May you and your
family have health and prosperity in the com-
ing year. Aureus would also like to thank you
for your support and friendship throughout
this past year.

Aureus Research Staff

**Aureus would like to welcome the
following team member!**



Alicia Connelly



CISCRP's Nation Medical Hero Campaign

CISCRP is running a new campaign promoting the mes-
sage "Volunteers in clinical research are the heroes in the
discovery of new medical treatments". In an attempt to
promote public awareness and trust in the clinical trial
industry, CISCRP is offering visual aids which can be dis-
played at your site. The materials are not labeled with a
specific sponsor or clinical study. The intent is to increase
patient education.

Are you looking for newsletters about subjects and their
Phase I-IV research experiences? These are also included
on the website. Or potentially you know a subject who
would like to share their research experience.

For more information on the Medical Heroes program,
please visit www.ciscrp.org



"Fear No Yellow Stickies Training Institute"

Training Courses Available in 2010!



Join us for incredible learning, networking, and
interactive experiences. For new coordinators, a
blended-learning opportunity to participate in
our online GCP training course prior to
attending the 2-day, interactive seminar!

Level 1 Blended Research Coordinator Course:
March 18-19, 2010
December 9-10, 2010
Contact Hours Available and only \$575.00/Person!

Level 2 Research Coordinator Course:
October 14-15, 2010
*Contact Hours Available; \$375 for 1 day or only
\$750 for both!*

Clinical Research Associate Training:
Monitoring Phase I Clinical Trials
May 13-14, 2010
Contact Hours Available and only \$899.00/Person!

New Upcoming Webinar in 2010!
GCP Update for Clinical Research Investigators
April 1, 2010

More Exciting Training Opportunities

Also available online, CD-Rom, and live seminar!

Clinical Research Coordinator Training:

Good Clinical Practice for the Clinical Research Professional

FDA Inspections:

What You Can Expect in an Audit

Designing Comprehensive Study Budgets and Contracts:

Maximizing Reimbursements, Minimizing Legal Risk

Clinical Research Associate Training:

Monitoring Phase I Clinical Trials

Investigator Training:

Good Clinical Practice for the Clinical Research Investigator

Investigator GCP Training for Medical Device Trials

GCP Updates for the Clinical Research Investigator

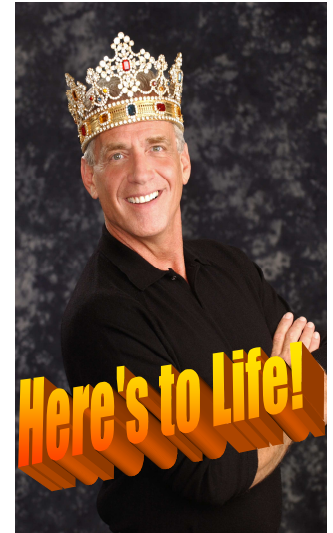
On-Site Training also available!

For information and registration visit www.aureusresearch.com
or call 1-877-284-1815.



Hello, my name is

?



So, what's in a name?

There you are, standing in a crowd at an Investigator meeting, a conference or the local holiday gathering when you see another person give you a megawatt smile and walk towards you. What's their name? You can't remember! Jim, Billy Bob, Mary, Dr. Something? You give your best fake smile as they draw closer and closer.

Now, you're starting to PANIC! Johnson, Smith, Jones? You know you should know them! As they extend their hand and call you by name, you respond with "Howw aarre Youuuu?"

Externally, you continue to make small talk and nice facial expressions while internally, your mind is screaming...What's their name?! Remember!

As you try to maintain eye contact, and without them noticing, you attempt to glimpse at their nametag. Your eyes continue the search until with great relief, you see the name and blurt out in a booming voice..."DR. MITCHELL! SO NICE TO SEE YOU!

Only now do you realize that unfortunately, and a common mistake, each name tag at this conference has been hung from a long lavalier and your smiling face is now at an extremely inappropriate social level!

Remembering names is a challenge for most of us but is an important skill in our relationships...personal and professional. So, here are some tips....

1. **Acknowledge** you can't remember their name. Don't try and fake it. They'll see through the *phony-baloney!*
2. **Ask** them to repeat their full name and if necessary to spell it for you.
3. **Associate** their name to a facial feature you're observing or to a specific item you are discussing. This can be a lot of fun and you don't have to tell anyone! Example: my last name is McDonald and you can see that my ears are large enough to support the *golden arches* over my head!
4. **Assume** they may not remember your name. Upon greeting, say your own name to relieve their suffering from "name anxiety".
5. **Apply** the above tips often so they become your natural behavior!

Have a GREAT day and a wonderfully joyous holiday season!

B



**2010 ACRP FDA Regions
Certification Dates for
Clinical Research Coordinators
And Clinical Research Associates**

Application Deadline for Spring Exam:

January 11, 2010

Exam Dates:

March 04-13, 2010 (check locations)

Certification is the formal recognition of clinical research professionals who have met professional eligibility requirements and demonstrated at least a minimal level of job-related knowledge and skills.

**Need Help Attaining or Maintaining
Certification?**

The FNYS Training Institute offers both live and online beginning and advanced topic courses!

**2010 SOCRA Certification
Offered in New Orleans, LA**

Application Deadline for Exam:

February 12, 2010

Exam Date:

March 27, 2010

The exam is being held at the Hilton New Orleans/St. Charles Hotel

In order to be considered for SoCRA certification, the applicant must be a current member of SoCRA working with GCP guidelines under IRB/EC/REB approved (or specifically exempted) protocols. Any questions regarding the eligibility requirements should be directed to the SoCRA Administrative Office.

See the SOCRA website for listings of additional test sites and testing dates.



 Congratulations Elaine Boos on becoming a *Certified Clinical Research Associate!*

***Do you know who GINA is?
What GINA is? Is it important to you?***

Terry Mitchell

Office Manager/Human Resource Manager

If you work in Human Resources or in and around the medical community, you have heard of **GINA**. GINA is an acronym for the *Genetic Information Nondiscrimination Act*.

As of November 6, 2009, this new Federal law prohibits discrimination in health coverage and employment based on genetic information.

Why is this important to you? GINA will work in partnership with the Health Insurance Portability and Accountability Act. GINA's employment provisions generally do not apply to employers with fewer than 15 employees.

It is however, critical to understand the new law as it applies to hiring, promotions, terminations of employment regarding genetic information.

An article recently published, referenced below offers insight into how GINA may affect you, as an employer, regarding health insurance carriers using genetic information to set rates and premiums, along with a myriad of confidentiality concerns.

Will GINA information gathered affect employees participating in a Wellness Program?

And then there is the 'Research' business side - How will GINA affect the Informed Consent process?

GINA may present situations where it is appropriate for researchers to discuss the provisions of the law with individuals participating in a research study or those considering study participation.

For more information, see the following guidance document prepared by the Office for Human Research Protections:

<http://www.hhs.gov/ohrp/humansubjects/guidance/gina.html> (URL),

<http://www.hhs.gov/ohrp/humansubjects/guidance/gina.pdf> (PDF).

Final FDA Guidance on Investigator Responsibilities Changes Little From Draft Guide To Good Clinical Practice Article

October 26, 2009

The final FDA guidance on investigator responsibilities released Oct. 26 differs little from the guidance released in May 2007 (see "FDA Clarifies Responsibility in Delegating Tasks," May 2007).

One of the few major changes in the final guidance is the supervision of field clinical engineers in device trials. The draft guidance said field engineers should be supervised by the sponsor and not by the clinical investigator. The final guidance states field engineers "should be supervised by the investigator because the field clinical engineer's presence or activities may have the potential to bias the outcome of studies, may affect the quality of research data, and/or may compromise the rights and welfare of human subjects."

The field guidance adds that "if the field engineer has face-to-face contact with subjects or if the activities of the field engineer directly affect the subject, those activities should also be described in the informed consent." Another addition to the guidance states that "for each study site, there should be a distinct individual identified as an investigator who has supervisory responsibility for the site. Where there is a sub-investigator at a site, that individual should report directly to the investigator for the site (i.e., the investigator should have clear responsibility for evaluating the sub-investigator's performance and the authority to terminate the sub-investigator's involvement with the study). The sub-investigator should not be delegated the primary supervisory responsibility for the site."

Caution Given on SMOs

The final guidance also adds that investigators "should be particularly cautious where documentation needed to comply with the investigator's regulatory responsibilities is developed and maintained by [site management organization (SMO)] staff (e.g., source documents, case report forms, drug storage and accountability records, institutional review board correspondence). A sponsor who retains an SMO shares responsibility for the quality of the work performed by the SMO."

According to the final guidance investigators should inform subjects "when medical care is needed for conditions or illnesses unrelated to the study intervention or the disease or condition under study when such condition or illness is readily apparent or identified through the screening procedures and eligibility criteria for the study. For example, if the investigator determines that the subject has had an exacerbation of an existing condition unrelated to the investigational product or the disease or condition under study, the investigator should inform the subject. The subject should also be advised to seek appropriate care from the physician who was treating the illness prior to the study, if there is one, or assist the subject in obtaining needed medical care." In its discussion of appropriate delegation of study-related tasks, the final guidance adds that ensuring an individual delegated a task is qualified includes state licensure where relevant. The guidance notes licensing requirements may vary by jurisdiction, such as states or other nations. In addition, "in all cases, a qualified physician (or dentist) should be responsible for all trial-related medical (or dental) decisions and care."

The guidance also notes that the trial protocol may specify the qualifications of individuals who are to conduct protocol-required tasks, such as a physician or registered nurse. In those cases "the protocol must be followed even if state law permits individuals with different qualifications."

The final guidance reiterates that investigators should be available to subjects during studies by phone or other electronic communications and adds the contact should be available "24 hours a day."

The final guidance also removed the detailed description of investigator responsibilities found in 21 C.F.R. §312 and 21 C.F.R. §812, noting sponsors and investigators should refer to those regulations, as well as 21 C.F.R. Parts 11, 50, 54 and 56. In addition to the requirements found in FDA regulations, the guidance also noted that some investigators may be responsible for submitting clinical trial information to clinicaltrials.gov.

Budgets and Contracts- The Benefits

Jill Petro

Senior Clinical Research Associate

Whether you are a research coordinator or a research manager, you may wonder if all the time and energy to develop Budget and Contract tools is worth the effort. I definitely believe it benefits both the Sponsor and the Site. We all know that the Contract & Budget negotiation often slows the initiation of studies, so tools to improve this process would be worth the initial investment.

If the Sponsor has developed an excellent contract that addresses all of their issues, as well as the Site's issues, the contract should need little negotiation. Since our goal is to work collaboratively and protect the subjects in a study, there really shouldn't be much we can't agree upon quickly.

If the Site utilizes a checklist and finds

a required element that is missing, it could be well worth the initial time invested because now they have protected their Site more fully by adding that element to the contract.

If the Sponsor uses a spreadsheet that includes procedure costs as well as other non-procedure time costs (e.g., CRF completion, Investigator data review time), their budget will be more likely to cover all of the costs a Site will incur by participating in the trial. Not only does it make the negotiation simpler for this trial, but it helps a Site to be financially stable to continue to work with them in the future.

If the Site uses a spreadsheet, they won't unintentionally forget to add in any items that will cost them money in completing the study. For example, if the Sponsor's template does not include dry ice, a Site might not even know yet if dry ice will be needed. By having it on the Site's template, it will

remind the Site to ask the Sponsor how often dry ice will be required.

Everyone involved in the Contract & Budgets review process is likely to benefit from an in-depth review of their process. Not only will everyone be more aware of the issues, each will feel more confident in the ability to do a thorough review. Their skills at negotiating will improve, because they know why they are asking for certain items. Overall, it is a win-win situation for everyone involved.

This article is part of a series. If you have any questions, please contact Aureus Research Consultants

For more information regarding advanced topics in Budgets and Contracts, consider purchasing our Online Intermediate Program at www.aureusresearch.com!

The Golden Glow is published by Aureus Research Consultants. Suggestions, Comments, and your contributions are welcomed and appreciated.

Please submit your ideas to jenniferd@areusresearch.com or contact her at 701-426-9034.



WWW.AUREUSRESEARCH.COM

Christmas Jokes:

Why did Santa's helper see the doctor?
Because he had low_elf_esteem!

Who sings "Blue Christmas" and makes toy guitars?
Elfis! Thank you, thank you very much.



Attention Louisiana Employers and Employees!

Your training could be free through the Louisiana Department of Labor!

Aureus Research Consultants, LLC has been approved as a training provider for Small Business Employee Training (SBET) Applications.

Employers meeting the criteria and providing proper documentation of training may be reimbursed for live classes and online programs.

Check out this tremendous educational opportunity at www.laworks.net or Call Bruce McDonald at 504-833-1528 For more information.

Quote of the Day:

Yes, Virginia, there is a Santa Claus. He exists as certainly as love and generosity and devotion exists, and you know that they abound and give to your life its highest beauty and joy.

editorial in the New York Sun, 1897, responding to a letter from 8-year-old Virginia O'Hanlon