We Need You!!!
A message from your Greater Pittsburgh Chapter President
Get Involved and Help the Chapter Ensure Continued Success

Our recent poll indicated that we want and need our local ACRP Chapter to continue and grow! The results of our survey are listed in the back of this publication. Thanks to all who participated, we truly appreciate your feedback and involvement!

If you have been wondering how to get more involved with our Chapter, now is your chance.

Taking advantage of one of our Chapter’s leadership opportunities is critical to the continued growth and success of the Greater Pittsburgh Area ACRP Chapter.

Volunteering your time and expertise to focus on specific initiatives, issues and programs of importance to our industry, as well as meeting the needs of our membership, is crucial. Through your continued involvement and support, you can help us reach some of our future goals of regional program development, Certification and scholarships for national events. Remember, our Chapter was formed in order to provide clinical research professionals a means for professional interaction, professional development, and networking and to provide ACRP benefits at the local level. Without your support and continued involvement, we cannot function as a Chapter.

Together we can accomplish common goals and achieve mutual benefits through our enthusiastic support of our Chapter.

If you are looking for a great opportunity, please contact our membership chair,

Patsy Carey at  Careypl@upmc.edu

Looking forward to a great year!

Best Regards,

Barb Early, RN, BSN, CCRC
Greater Pittsburgh Area Chapter President 2010-2012
Jennifer Koehrsen, MS CCRC

Graduated with an MS in Experimental Methods with a specialization in Social Psychology from Ohio University in 2004 and began working for Allegheny Singer Research Institute (ASRI) as a Coordinator of Research with the Allergy, Asthma, & Immunology and Pediatrics departments in November of 2004.

She worked for the ASRI-WPAHS Institutional Review Board Research Integrity Specialist and became the Administrative Director of Interdisciplinary Research and Education for ASRI in 2011. Jennifer currently serves as a Vice Chair for the ASRI-WPAHS IRB.

- Began working for Allegheny Singer Research Institute (ASRI) as a Coordinator of Research with the Allergy, Asthma, & Immunology and Pediatrics departments in November of 2004.
- Became a Certified Clinical Research Coordinator with ACRP in 2007.
- Began working for the ASRI-WPAHS Institutional Review Board in 2010 as a Research Integrity Specialist.
- In 2011, became the Administrative Director of Interdisciplinary Research and Education for ASRI.
- Established a hospital system-wide research education program that includes bi-monthly lectures on various topics related to clinical, laboratory, and animal research as well as teaching a half-day course on the Federal Regulations and GCP for clinical research.
- Serves as a Vice Chair for the ASRI-WPAHS IRB since 2011.
- Volunteers at the Pittsburgh Zoo & PPG Aquarium as a docent and greatly enjoys educating the public about animals and ways to help protect their environment.

Future Events

- September - Elections for new officers will be held this year. Look for forms in your email inbox.

- October 5th - Come down to Hidden Valley for an evening of good food and speakers, then spend the night at a special rate and attend the Autumn Fest at Seven Springs. The festival offers featured crafts, hayrides, Autumnfest Buffet, alpine slide and entertainment.
Do You Have a Clinical Quality Management Plan?

Mary Stefanick, RN, BSN, CCRC

Having a written Clinical Quality Management Plan (CQMP) is not only good clinical practice, but is frequently being required by sponsors for funding awards. Are you ready to meet the challenges of developing and writing an effective and achievable plan to assure quality for clinical research at your facility?

Here are some basic tips to get started:

Basic elements of a CQMP must include quality assurance and quality control activities.

- **Quality control** is what is ongoing in your *day to day* operations that assure quality in your research. Many of these activities are based on standard operating procedures (SOPs) that have been (or should be) developed for your research department. A few examples of helpful SOPs might include: informed consent procedures, general laboratory procedures, training qualifications of staff, and data entry verification procedures.

- **Quality assurance** is achieved by performance of *scheduled periodic reviews* of a chosen percentage of subject records and regulatory files. Development of tools to assist with quality control may include checklists with a focus on study specific Key Quality Indicators (KQI) and regulatory inventory checklists. KQI should focus on the accuracy and compliance of specific study protocol activities that directly impact the health, safety, and rights of human subjects and the accuracy of data specific to study endpoints.

A good CQMP is effective only if the reviews are well documented so trends and patterns can be seen and overall improvements and revisions can be made. It is suggested that a separate binder for quality control for each trial is maintained to provide a ‘go to’ place for assessing and maintain the highest quality possible. At least yearly, and more frequently as needed, the overall CQMP itself should be reviewed and revised as appropriate.

Remember this equation:

*Good CQMP = Good quality research = Good quality data = more opportunity for addition research!*
Events Round-up

**Ethical Issues in Human Subjects Research**

March 20th, 2012

Holiday Inn University Center

Judy Stone, MD
Infectious Disease
Author

The evening began with a presentation on current hot button issues such as COI and participant recruitment. Dr. Stone followed with a very compelling and provocative presentation about issues in research ethics that are occurring not only domestically but span the globe. Dr. Stone’s presentation of the upcoming pediatric Anthrax trial and her well documented discussion of the disparities in health care dollars for medical research versus actual life-saving international health care initiatives was interesting and inspiring.

Judy Stone, MD is an infectious disease specialist, experienced in conducting clinical research. She is the author of *Conducting Clinical Research*, the essential guide to the topic. She survived 25 years in solo practice in rural Cumberland, Maryland, and is now broadening her horizons. She particularly loves writing about ethical issues, and tilting at windmills in her advocacy for social justice. As part of her overall desire to save the world when she grows up, she has become especially interested in neglected tropical diseases.

---

**The Institutional Review Board: An Analysis of the Role and Responsibility of a Regulatory Entity**

August 22nd, 2012

West Penn Hospital

Peter Ledwich, BA
Manager, ASRI-WPAHS IRB

This interesting and informative presentation was an in depth look at conducting clinical research interaction with the Institutional Review Board. This presentation consisted of historical events that helped create formal regulations to govern research, the IRB’s structure and role in serving the institution, investigators, and study subjects, and the IRB’s criteria for approval at the three levels of review. Peter Ledwich’s goal was to remove the veil surrounding the IRB and shed light on the makeup of the board, how determinations are made, and roles and responsibilities bestowed upon the board by the Federal Regulations.

Peter Ledwich is the IRB Manager of Allegheny Singer Research Institute. As a Political Science major at the University of Pittsburgh, Peter obtained a position with the IRB at Carnegie Mellon University as a Document Management Specialist. He worked his way up to a Regulatory Compliance Officer, preparing him for his current position. Since joining Allegheny Singer Research Institute Peter has overseen system-wide research integrity, protection of human subjects’ rights, safety and welfare, and approval of research conducted at several local hospitals.
In order to assess the interest in the local chapter from the members, a survey was sent to all current members. The results using SurveyMonkey are below.

Why did you become a member of the local ACRP?
- 92% said for professional growth, followed by joining for networking events and CEUs.

Do you feel that you have benefited from being a member of the Greater Pgh. Chapter of ACRP?
- 44.4% said they felt a moderate benefit
- 10 people said small benefit, 2 people said no, and 3 said great

The Greater Pgh Chapter of ACRP traditionally tries to offer 4 events per year that will allow members to get CEUs. Have you attended one or more of these events?
- 81% of responders attended events

If the Greater Pgh Chapter of ACRP offered a one day event with multiple speakers including a business meeting and opportunities to network on a once per year basis, instead of four meetings per year, would you be likely to attend?
- 69% of responders said yes

The Greater Pgh. Chapter of ACRP traditionally tries to offer a twice yearly newsletter. Have you read and enjoyed the newsletters?
- 17 people responded yes
- Most people who did not read it stated that it's because they didn't receive it

What types of articles would you like to read in a research related newsletter?
- Hot Topics, Research Tips, CEU opportunities

Would you like to continue to have a local chapter of ACRP in Pittsburgh?
- 92% said yes

How much of your time could the leadership of The Greater Pgh. Chapter of ACRP expect from you to help the organization to succeed?
- 11.5% could be an officer
- 19.2% could be a committee chair
- 34.6 could be a committee member
- 53.8% could attend a yearly meeting, give feedback and promote CTSI
- 23.1% do not want to be involved at this time.

### Responders’ Statistics—Twenty-seven of 86 members responded.

<table>
<thead>
<tr>
<th>Years in Research</th>
<th>Years in National ACRP</th>
<th>Profession</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over 16</td>
<td>40.7%</td>
<td>0-5</td>
<td>38%</td>
</tr>
<tr>
<td>10-16</td>
<td>29.6%</td>
<td>6-10</td>
<td>34%</td>
</tr>
<tr>
<td>6-10</td>
<td>22%</td>
<td>11-5</td>
<td>26.9%</td>
</tr>
<tr>
<td>0-5</td>
<td>7.4%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Coordinators 55.6%
Pis 14.8%
Project Managers 18.5%
CRAs 7.4%
other 22.2%