

**CoAPCR (Consortium of Academic Program for Clinical Research)  
Teleconference Minutes (Distributed 9/23/14)  
September 12, 2014  
2 PM EST**

**Teleconference Participants:**

Attendees (who responded to a verbal roll call):

Carolynn Jones, Steve Sonstein, Barbara Gladson, Sara Perkel, Regina Ponder, Cris Wells, Carl Hornung, Jim Parmentier, Joan Butler, Margie Neidecker, Barbara Pennington, Greg Koski. However, fifteen (15) participants were noted on the electronic call culmination records.

**CoAPCR President Carolynn Jones (PCJ)** opened the meeting just minutes after the hour and requested that participants identify themselves.

1. **PCJ introduced Greg Koski, M.D., ACRES** who provided an updated overview of activities conducted by ACRES to date:
  - At DIA, ACRES held a Global Stakeholders Consultation with Freda Lewis Hall (Pfizer/IOM) presenting the keynote address. The focus of that meeting was site accreditation. The next phase of the progress moving forward included a process to define global standards of excellence for clinical research sites, led by teams, including Quintiles, Pfizer and members of ACRES team. This group will form 7-10 Standards Development Teams. A forthcoming IOM report from the Collaborative Working Group on Accreditation of clinical research sites validates what ACRES aims to achieve in site accreditation. The plan is to pressure test the accreditation tool in 2015 and begin working with sites in early 2016. Dr. Koski reported that responses from a comment of Pharmaceutical CEOs and the collaborative was- "why hasn't this been done by now?"
  - A secondary initiative by ACRES is working with its IT Consortium to study and develop a universal interface for regulatory agencies, sites and industry, using a single sign on approach. ACRES is working with an industry IT partner in this vision.
  - Currently ACRES has 65 strategic (including CoAPCR) and growing. The hope is to have members of the Standards and Development teams come from among these members. ACRES is beginning to acquire funding to achieve their large goals.
  - ACRES is interested in utilizing their efforts as a platform to support their strategic alliances (e.g., CoAPCR). Partners are welcome to share their current infrastructure. ACRES is already a member of almost 65 groups on LinkedIn. The ACRES contact is Mary Cobin.

**2. Following Greg Koski, Stephen Sonstein of CoA discussed**

- The Accreditation Process Presented in Two Parts:
  - *The consortium approached the Commission on the Accreditation of Allied Health Education Programs, CAAHEP, the umbrella accrediting body for academic programs about a year and a half ago requesting that they recognize clinical research as an academic discipline and as a profession. The intent was to lead to the development of an accreditation process for academic programs that educate clinical research professionals. The request was approved. The [Clinical Research Professional] is now officially listed as a profession and a committee on accreditation has been formed for the development of standards and guidelines to be used to accredit academic programs in clinical research. The CoA is the sponsor of that committee on accreditation. They are two independent bodies. The CoA is a committee that reports to CAAHEP. The consortium is the sponsor. There are two commissioners appointed to CAAHEP: one who is the Chair on the CoA and a second who is appointed by consortium as the sponsor. The second position is open. An announcement was given to teleconference participants such that if any were interested in serving as commissioner to CAAHEP, to please inform PCJ. (Steve Sonstein serves as the Chair of the CoA and as such is the Commissioner from the CoA to CAAHEP.)*
  
- A. The accreditation process is potentially a global process. There are many other academic centers in other areas of the world which are significant to the overall picture.

Individuals currently serving on the CoA accreditation team are Bill Pickard, Campbell University, Carolynn Jones, Ohio State University, Barbara Gladson, Rutgers, Regina Ponder, GateWay Community College, Cris Wells, Arizona State, Honoria Silva, IFAPP (which represents educational entities throughout Latin and South America), Carl Hornung, University of Louisville, Sarah Perkel, Drexel. And we have representatives from ACRP, Terri Hinkley, RAPS, Sharon Carnitas Vadim Tantsura of SCDM. The Chair from the ACRP Certification Board has also been invited.

Standards and guidelines developed by the joint task are being translated into a set of generic core competencies to be incorporated by the academic institutions. Focus is being given towards accrediting clinical research management programs as well as regulatory affairs both with respective criteria to be met. There's still much work to be done in defining the standards as well in defining the self-study process.

The timeline for completion of the accreditation process is projected for Spring 2015 and must be submitted to CAAHEP for approval with a possible initiation date of September 2015.

- S. Sonstein has been awarded a Sabbatical for Winter 2014 Term which will allow him to dedicate time to the CoA.

#### B. Per S. Sonstein – The Second Dimension to the Accreditation Process

- Three organizations who have agreed to be Supporting Members will offer active members to the CoA: ACRP, RAPS and SCDM. Currently, none of these organizations require academic program as preparation for certification.
- Certification references personnel; accreditation references institutions. We've been interested in developing a relationship with these entities to examine strategies for linking certification with education. Considerable progress has been made with ACRP to date. There's much work to be done overall.
- ACRP will allow graduates of CoAPCR programs with an internship experience to reduce their requirement of two (2) years of experience to one (1) year of experience.
- Transparency issues within the academic process need to be addressed.
- Part of the overall accreditation process will involve data collection on student activity concerning numbers enrolled, etc. in an effort to better provide the statistical value of enterprise (CoA/CoAPCR) involvement impacting multiple stakeholders.
- PCJ recommended more collegial membership involvement for CoAPCR sustainability and requested that S. Sonstein review the Supporting Members process.
- PCJ introduced the possibility of the CoAPCR designate Commissioner to CAAHEP as Dr. Carlton Hornung. Dr. Hornung, recently retired from University of Louisville has been tapped to consider this position since he recently attended a CAAHEP meeting in August (in Charlotte NC) on behalf of Dr. Sonstein and has a gestalt for the processes.

### 3. Membership Report- Joan Butler from GW

- Membership drive is in process and will be in pursuit through September 2015. To date a total of 5 membership dues have been received. The annual dues date for already established members is October 1, 2014.
- Dues have been received for six (6) institutions.
  1. Eastern Michigan University
  2. Seneca College
  3. Boston University
  4. Regis
  5. U. of North Texas Health Sciences

- 6. Arizona State U.
- ADDENDUM- Since the call – 3 sites have reported their dues are in process or in the mail:
  1. Ohio State University
  2. University of North Carolina, Wilmington
  3. St. Cloud State University (**Received**)
  4. Durham Tech
  5. Northwestern Univ
  6. Midstate Technical College
  7. Rutgers
- A second call for membership will be emailed to the 94 sites that are offering programs.
- The CoAPCR website will be updated to reflect current membership status on October 15, 2014.

**4. Treasurer’s Report- Reported by PCJ on behalf of Margie Neidecker**  
(Ms. Neidecker had to leave the teleconference early for another obligation.)

CoAPCR paid a \$3000.00 Annual Membership dues to CAAHEP in September 2014.

- Margie Neidecker has reported that the balance of the CoAPCR account is \$930.00; this is what is remaining after paying the invoice to CAAHEP and with the deposit of 5 membership dues.
- A PayPal system has been uploaded to the CoAPCR website to enable member payments
- The three sponsoring members have been invoiced: ACRES, RAPS and SCDM, and are pending.
- The 501c3 status of CoAPCR is pending IRS designation (a lengthy process) The non-profit application was transferred from Michigan to Ohio in Spring 2014.

**5. Competency Research- Stephen Sonstein**

- After publication of the Joint Task Force Competency Paper in Clinical Researcher, Applied Clinical Trials, MAGI’s Journal of Clinical Research Best Practices and Centerwatch White Papers, the next phase of developing a survey instrument for validating the competencies as a self-assessment on level of application and importance is evolving. Several entities, including University of Michigan are piloting the survey. There are fifty-two (52) competencies within each domain.

- PCJ and S. Sonstein had a conference call with Fiona O'Neill and Helen Pidd of the UK National Institutes of Health who are embarking on re-examining their previously published competencies. They wanted to utilize the JTF Competencies and will pilot the survey amongst their UK constituents. They plan to pull to have something by late Fall, 2014.
- The overall goal is to framework the core competencies for self-assessment on a zero to five scale and hopefully use the results to refine and define the roles for the various roles within the clinical research enterprise.
- The eventual finished product could become an excellent tool contribution for institutions to utilize in creating job descriptions, etc.

## **6. Educational Benefits of Membership**

- PCJ suggested that we transform our website to have a 'members only' section to provide an avenue for members to share information on educational offerings, webinars, resources and slides.
- S. Sonstein suggested that sites also feature distinct course offerings that students from other institutions may could take for credit and transfer those credits to their programs.
- PCJ reported that the Voice Thread demonstration by Barbara Gladson at the ACRP meeting of the CoAPCR has led to Ohio State adopting this teaching tool in its courses.
- PCJ and Steve discussed the importance of beginning to gather data from member sites on program metrics, such as numbers graduated, numbers of students who have progressed into clinical research careers (or advanced in their careers) as a result of being in these programs. The value-added aspect of CoAPCR's contribution to the Research Enterprise should be recognized.
- The consortium could possibly function as a clearinghouse for online courses that are utilized amongst universities and colleagues for various uses including continuing education credits. Creation of a subcommittee was suggested to help facilitate promulgation of these courses. B. Gladson volunteered and is looking for others to assist.
- ACRP offers multiple new online courses, which could be incorporated into academic student courses, through independent studies.
- Per PCJ, the goal is to reach all academic centers offering clinical research programs for participation.

## **7. By-Laws- Jim Parmentier and Sara Perkel**

- Jim brought up that we needed to finalize any outstanding issues with the bylaws. Sara Perkel agreed.

- PCJ stated that she had a near final draft that had come out of our Annual Meeting when the bylaws were discussed and vetted. She will send those to Jim and Sara.
- This version has been filed with Margie Neidecker for the purpose of moving forward with non-profit business
- The bylaws of the organization should lack granularity since there are ongoing and evolving activities of the organization. The re-drafting of bylaws for operational activities may not need to be included. (Note- Margie Neidecker related to C. Jones that we had decided to not put the financial detail of member dues in the bylaws themselves, e.g., amounts, so that has been pulled out).

The teleconference adjourned about 3:10 P.M. EST.

The next teleconference will be November 14, 2014 at 2pm EST.