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CoAPCR (Consortium of Academic Program for Clinical Research) Teleconference Minutes for November 14, 2014 1 PM EST

Teleconference Participants:

Twenty-three (23) participants. Stephen Sonstein, Honorio Silva, Greg Koski, Cris Wells, absent with notice.

CoAPCR President Carolynn Jones (PCJ) opened the meeting at 1pm EST.

1. **WELCOME.** PCT welcomed the group and suggested that the group do business related agenda items first, and then proceed to our guest speaker, Jean Feagin who will present on Regulatory Affairs and the Association of Graduate Regulatory Educators (AGRE) group's work.
2. **MEMBERSHIP/TREASURY REPORTS.** A report on the membership committee and treasury was made. Joan Butler reported that CoAPCR has received dues from 18 institutions and several are "in process". She is encouraging institutions to get their membership dues in by the end of the year. Moreover, four groups have stepped up to be Supporting Members – ACRP, SoCRA, RAPS and SCDM. We have received dues from ACRP and SoCRA so far. Margie reported that the account is up to \$3800 and that she had made a payment of \$3000 for our annual dues to CAAHEP.
3. **ANNUAL MEETING.** The consortium is planning to hold its next Annual Meeting at the ACRP Annual Global Meeting being held in Salt Lake City Utah in April 2015. Invitation was given to CoAPCR members with respect to the formation of a planning committee for our Annual Meeting there- which should be about ½ day during ACRP (or prior to). Terri Hinkley of ACRP will begin discussing how to fit CoAPCR into the planning for the ACRP Meeting- with respect to meeting rooms, timeframes, etc.
4. **BOARD NOMINATIONS.** Board nominations for President was raised by PCJ explaining that her term ends in one year. The group was encouraged to be thinking in this direction. A President-Elect position needs to be filled. Margie Niedecker indicated that her term as Treasurer completes at the end of the academic year and is permitted to serve one more two-year term in accordance with the current by-law. PCJ referenced Barbara Gladson for comments regarding board member positions. Ms. Gladson deferred subject matter discussion as she was not informed at this time.
5. **MEMBERSHIP COMMITTEE EXPANSION.** PCJ indicated that in terms of the membership committee it would take a village of individuals, a dedicated effort for additional members, thanks to Joan Butler. **We are looking for 2 additional individuals to be on the Membership Committee to lead a**

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- segment of this initiative.** More emphasis is needed with this committee to invite and recruit other types of members in the sustaining membership category and to reach out to academic sites who have not joined yet. Ms. Gladson raised the issue of recruits in Europe and requested information on handling these respective scenarios. Ms. Gladson sent a list of members who have academic certificate, diplomas and degrees listed with PharmaTrain that should be targeted to join us. PCJ discussed an academic program in Scotland that has a satellite program in China as well as UK (Edinburgh-Napier University, Gordan Hill). She has been in contact with them and hope to have them join us. There seems to be great interest across the board to be inclusive with ex-USA academic program membership. CoAPCR has a Google Docs list that is being maintained with updated lists of programs and contacts.
6. **LINKS TO ASSOCIATIONS.** A non-agenda item was raised by PCJ: There are opportunities to link academic programs with Clinical Research Association training initiatives. Proactive behind the scenes discussions are being encouraged to explore how academic programs can link with Associations, like ACRP and DIA. Open comments were welcomed. No individual responses were garnered. PCJ has reached out to Esther Daemen to investigate ways she can incorporate some of the ACRP training initiatives in her institution and will share what she finds.
 7. **JTF CORE COMPETENCY SURVEY MONKEY.** PCJ gave an update on the Joint Task Force survey research to validate the published core competencies for Steve Sonstein who could not be on the call. Steve has piloted the survey in his institution at Eastern Michigan and some other places and has a graduate student working on analysis of those results. He has circulated the Survey Tool, including a letter of invitation, the demographic section and the core competency survey which will use the Survey Monkey Platform. The JTF Committee are currently reviewing the tool and submitting edits to finalize the survey. There are hopes that it will be widely distributed. Member institutions are encouraged to distribute the survey within their institutions as well as through our affiliated Associations. There have been discussions with ACRP about housing the JTF Survey. Terry Hinkley responded that she had discussed this with Jim Thomasell at ACRP and there was great interest and that she would follow up with Steve later about this.
 8. **ACCREDITATION.** PCJ stated that the Commission on Accreditation (CoA), led by Steve Sonstein is working on editing the Standards document. This will ultimately be sent to CAAHEP for final approval in winter with a target for submitting requests for interest in proceeding with accreditation activities occurring by summer. Great progress is being made but there is still a lot of work to be done. Carl Hornung is the Commissioner representing the CoAPCR to CAAHEP and Steve Sonstein is the Commissioner representing the CoA to CAAHEP. The CoA will be having a teleconference later this month

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and have been actively editing the standards document. Steve Sonstein and Carl Hornung will be attending the CAAHEP meeting in January.

ACRP STUDENT MEMBERSHIPS. Megan Balkovic, Director of Membership with ACRP provided a brief update on the student membership drive. The focus is on helping to develop a new student model that can be replicated. For example, identifying and accentuating student needs and how ACRP/Research Professionals can accommodate their needs. Students receive a membership discount rate. There will be focus on communications with academic programs for the sake of added value reciprocity. Comments are welcomed. PCJ referenced reaching out to Esther Daemen with respect to this initiative as well. The director responded that she would touch base with Esther since she will be present in the corporate office the forthcoming week.

9. **KEYNOTE SPEAKER.** PCJ followed and gave the floor to Jean Feagin to lead discussion on AGRE. Ms. Jean Feagin provided a historical overview through their organization's development and formation of regulatory core competencies (which initiated in 2010 and were approved in 2013). Ms. Feagin shared that in 2010, France Richmond, at USC, and contacted Graduate Programs to discuss cooperative initiatives. The meeting was held in San Diego and was attended by about 20 individuals representing fifteen (15) different programs with curriculum focused on Regulatory Affairs. Differences as well similarities were discovered. In 2011, late summer, Ms. Feagin met with Steve Sonstein which culminated in Barbara Gladsen attending the AGRE meeting in Seattle. Communications began between the two organizations. Jean's group is now incorporated as of April 2010 and were preparing to file a 501c3 application with the IRS. (Luckily, it has since been learned this past summer that the IRS only requires a shorter, three page form, to her delight.) The group would like to remain independent of CoAPCR and continue to focus on their unique competencies in Regulatory Affairs.

Ms. Feagin discussed the variability of curriculum and requirements of graduate regulatory programs and provided numerous examples, which also primarily focused on medical devices and some that focused primarily on drugs and combination product development. The Regulatory Affairs Core Competencies have defined five competency domains that were critical to a respective competency. The five areas noted were (a) regulations, (b) quality, (c) clinical, (d) strategy, and (e) communications. Examples of usage were provided. The publication citation for the competencies is: **Shire S, Swanson C, Drago D, Feagin J. "Core competencies Provide a Roadmap for Strengthening Regulatory Education." *Regulatory Focus*, September 2014. Regulatory Affairs Professional Society.** Ms. Jean will share the information with PCJ for prospective comparative analyses to the CoAPCR/JTF Core Competencies. Cross talk was opened to the participants. Bill Pickard, Campbell College,

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offered conversation and an interest in reviewing the competencies. Carl Hornung offered comments with regard to epidemiology and statistics input. Ms. Jean addressed his comments.

10. PCJ offered final comments and eventually adjourned the meeting.

The teleconference adjourned about 2:13 P.M. EST.

The next meeting is slated for January 23, 2015.