

From: Clegg, Patsy M SCC-CHSE-PC <patsy.clegg@shell.com>
Sent: Thursday, November 20, 2003 9:21 PM (GMT)
To: Beatty, Patrick (PatrickBeatty) <PatrickBeatty@chevrontexaco.com>; mfitzsimmons@steptoe.com; lynn.b.russo@exxonmobil.com; Bruce Jarnot <jarnotb@api.org>; benzconsort-oc@listserve.api.org; benzconsort-tc@listserve.api.org; toddm@api.org; brian.e.doll@exxonmobil.com; myron.c.harrison@exxonmobil.com; Burnett, Don <burnetdm@bp.com at burnetdm@bp.com>; michael.johnston@conocophillips.com
Subject: RE: BHRC-TC... Recommendation to Combine SRP & ERP External Panel s

I definitely support keeping the SRP and ERP as separate organizations. I believe that we would definitely create a conflict of interest by merging them. There serve 2 very distinct functions.

As far as resolution, I would vote for a quick resolution - either ballot or conference call. There is a sense of urgency about finding a chair - seems to me that one of the existing members would be appropriate - and then finding an additional new US member. We have 3 protocol changes proposed. The ethics review is as critical as SRP and IRB.

You may consider this email my vote for a separate SRP and ERP.

Regards,
Patsy

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-----Original Message-----

From: Beatty, Patrick (PatrickBeatty) [mailto:PatrickBeatty@chevrontexaco.com]
Sent: Thursday, November 20, 2003 12:27 PM
To: mfitzsimmons@steptoe.com; lynn.b.russo@exxonmobil.com; Bruce Jarnot
Cc: benzconsort-oc@listserve.api.org; benzconsort-tc@listserve.api.org; toddm@api.org; brian.e.doll@exxonmobil.com; myron.c.harrison@exxonmobil.com
Subject: RE: BHRC-TC... Recommendation to Combine SRP & ERP External Panel s

My turn to weigh in. I agree that we should stick with our original structure. I also think that rather than debate the issue via e-mails that the Oversight Committee is the appropriate forum for discussion and a final decision. To that end I would like to request that the Oversight Committee be polled as to whether they wish to address this issue quickly or wait until the next scheduled conference call in December. (Don, Patsy, Lorraine take note.) The conference call should be advertised so that others can make their opinions known. Mark should be a mandatory participant in the discussion. Also, the members of the ERP should be apprised of the situation and their input solicited. There is a pragmatic question of a chairman for the Panel that will need to be addressed if we continue with the present structure.

Patrick

-----Original Message-----

From: mfitzsimmons@steptoe.com [mailto:mfitzsimmons@steptoe.com]

Sent: Thursday, November 20, 2003 8:13 AM
To: 'lynn.b.russo@exxonmobil.com'; Bruce Jarnot
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Subject: RE: BHRC-TC... Recommendation to Combine SRP & ERP External Panel s

I tend to agree with Lynn. Like it or not there are going to be people out there who will want to misinterpret and criticize the study regardless, and I think it is important that "the integrity" of the effort be maintained. Perhaps Dr. Brody and or others would have thoughts on a replacement.

-----Original Message-----

From: lynn.b.russo@exxonmobil.com [mailto:lynn.b.russo@exxonmobil.com]
Sent: Thursday, November 20, 2003 11:05 AM
To: Bruce Jarnot
Cc: benzconsort-oc@listserve.api.org; benzconsort-tc@listserve.api.org; toddm@api.org;
brian.e.doll@exxonmobil.com; myron.c.harrison@exxonmobil.com

Subject: Re: BHRC-TC... Recommendation to Combine SRP & ERP External Panels

Bruce, While I'm not on the Technical Committee I receive their emails as the Communications Committee Chair. And from that perspective I strongly disagree with the proposal to combine the panels. I don't take exception to them meeting/working together, but feel quite strongly that we need to demonstrate a separate, independent ethics review capability. I would also prefer identifying a replacement for Baruch so we have 3 ethicists to consult.

The ERP was established to ensure independent ethics advice on the protocols and now on any suggested revisions/changes. For that purpose, we do need a separately constituted group. We do not want it to appear that the ethics advice is weighed with input from the science advisors to come to a recommendation. The structure we have now which gives equal weight/voice to the ERP and SRP makes a very strong and good impression on external folks. I would also like to see Baruch replaced since the original concept was to include Europe, China and the US to reflect any different approaches reflected in their different cultural norms.

That said, the way the SRP and ERP worked at Asilomar is fine. For a routine annual review that has not raised any ethics issue that worked well. But we do need to preserve the option for an ERP review, as spelled out in the original agreement on the consortium structure.

Lynn

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Subject: BHRC-TC... Recommendation to Combine SRP & ERP External Panels

11/20/03 09:43 AM

Benzene Health Research Consortium (BHRC) Technical Committee -

Baruch Brody today resigned from the Shanghai Health Study, stating "i have been very ill and have developed esrd [end-stage renal disease] and that precludes extensive out of town work. good luck on the remainder of the project - bab".

Now that the work load on both ethics and scientific review panels has moderated, I would like to recommend that these external panels be integrated under the leadership of Jerry Rice. Both groups worked extremely well together in this fashion at the August Asilomar meeting, and "topic lead" can still be deferred to members having that specific expertise - as currently done with issues regarding biostatistics, molecular markers, industrial hygiene and other specialties within the science review panel.

If so desired by the Consortium as a reasonable solution to Baruch's resignation, Jerry Rice has agreed serve in this combined capacity (suspecting there might have been a chronic debilitating health issue with Baruch, I tested this possibility with Jerry in late October).

Best Regards - Bruce.

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