

From: Beatty, Patrick (PatrickBeatty) <PatrickBeatty@chevrontexaco.com>
Sent: Saturday, January 10, 2004 12:19 AM (GMT)
To: benzconsort-tc@listserve.api.org; mfitzsimmons@steptoe.com; jarnotb@api.org; Matt Todd <ToddM@api.org>
Cc: Benzene OC listserve (E-mail) <BenzConsort-OC@listserve.api.org>; lynn.b.russo@exxonmobil.com; Lorraine Twerdok <Twerdokl@api.org>
Subject: Replacement for Dr. Brody
Attach: ethics r&r final.doc

All,

I am writing this to bring us back on track in the endeavor to fill Baruch's place on the ERP. The premise behind the e-mail that Bruce just sent out to the Technical committee members (after discussion with me yesterday, Thursday) is in error. We have been proceeding on the premise that the consortium would identify the replacement. I believe now (something that came to me early this morning as I lay in bed staring at the ceiling; something I do frequently) that this is at odds with the Roles and Responsibilities document for the ERP (attached) and with the general concept of how the two Review Panels would handle their membership once they were initially formed. Although the R&R document does not explicitly address replacing existing members (an oversight), I believe that it is clear that this should fall to them with advice from the Oversight Committee.

In other words, now that the ERP has been formed it is their right and responsibility to select the new member. Dr. Idanpaan-Heikkila has suggested a slate of potential replacements and Baruch has apparently endorsed Dr. Lombardo, identified by Myron Harrison. The R&R document says that the ERP may take suggestions from outside about its members, but the final decision is theirs.

I suggest that Bruce contact the ERP members including Baruch (Since he seems to be continuing his academic career, I would offer him the ability to be involved in choosing a successor.) to offer his services as staff person to facilitate their decision process. The ERP should decide how to prioritize the individuals on the list from Dr. Idanpaan-Heikkila as well as Dr. Lombardo and make initial contacts to determine their interest and availability. I know that at least one of them has worked with Dr. Idanpaan-Heikkila on a CIOMS committee. We already know that Dr. Lombardo appears to be interested. I am somewhat concerned that Dr. Lombardo may have the impression that we have chosen him to replace Baruch. I don't want him to get the wrong impression.

Even though this may slow things down a bit in reconstituting the Panel I believe that we need to continue on the path we established in order to avoid the perception of undue influence. In the meantime, I see no reason why the current two members of the ERP cannot provide any necessary approvals of protocol amendments, IRB wording, etc.

I apologize for the false start on this process, but as I have said above, I believe that we inadvertently started to overstep some of our own procedures. Do we need to have a conference call of the Oversight Committee on this matter (with Tech Comm. Participation)? I say Oversight Committee, because although the TC is the liaison with the ERP, this is a policy matter that supersedes the TC role.

Please respond to me ASAP regarding the need for further discussion.

Patrick

<<ethics r&r final.doc>>

Shanghai Health Study Review Panel Roles and Responsibilities

Ethics Review Panel:

Membership: The initial membership of the Ethical Review Panel (ERP) will be determined by the Business Oversight Committee. Members will have expertise in bioethics. Following initial formation, the ERP will be responsible for adding appropriate members up to its authorized limit. The Board may seek advice from others, including a Consortium Oversight Committee, on filling its authorized limit and may request an increase in that limit. The ERP should have at least three members; one each from the U.S., Europe, and China.

Responsibilities: The responsibility of the ERP is to make the recommendations necessary to ensure that the research conducted under this program meets internationally accepted ethics standards and reflects relevant cultural or other patterns in Shanghai. To meet this responsibility, the panel: (1) reviews and approves the protocols and consent forms before the research commences to ensure that recommendations of the earlier ethics review process have been incorporated; (2) reviews any changes in the protocols or the consent forms before they are implemented; (3) reviews, at periodic in-person meeting, the conduct and progress of the research to see that the ethics standards are being followed; (4) responds, on an as-needed basis, to issues raised by the Principal Investigators, the Scientific Review Panel, or the Consortium. Its recommendations will be given to the Oversight Committee who will distribute them to the appropriate individuals and who will oversee any response to them.

Meetings: The Ethics Review Panel will have an annual meeting as described above to review conduct of the research as it relates to ethics issues. Members will also be invited to attend the Consortium Annual Meeting. All other business will be conducted by conference calls and/or email exchanges.

Interactions: In order to facilitate interaction with other bodies: (1) the chair of the ERP and SRP (or his designee) will be an ex officio member of the SRP and ERP, respectively, and will attend its meetings and participate in its conference calls; (2) the Principal Investigators will be responsible for submitting proposed changes and annual reports to the ERP through the Technical Committee; (3) the ERP will be available to respond to concerns raised by the SRP, Oversight Committee, Technical Committee, Communications Committee and Principal Investigators.

Support: The Oversight Committee will provide to the Ethics Review Panel reasonable support to accomplish its mission including: (1) costs of travel to the annual meetings (one or more of which may be in Shanghai) and costs of running

Final
12/11/02

that meeting; (2) costs of the conference calls; (3) consulting fees for the members and the chair at an agreed rate; and (4) support staff to facilitate the activities and communication needs for the ERP.