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From: Cagen, Stuart Z SCC-HSE
</O=SHELL/OU=MSXSCC/CN=RECIPIENTS/CN=SC724012>
Cc:
Bcc:
Received Date: 2003-11-27 18:41:44 GMT
Subject: RE: Shanghai ERP - Baruch Brody has resigned due to ill health

Patrick and Bruce:

These are all excellent suggestions and I don't think we would go wrong with any of them.

Things to consider:

Special value of having US gov't employees ? Lepay (FDA) or Wendler (NIH). How about the value of having a MD,JD: Clayton.

Need to decide sometime soon to have the new person catch up and then be up to speed in time for protocol amendment.

Stuart

Stuart Cagen

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

From: idanpaanj@who.int [mailto:idanpaanj@who.int]
Sent: Thursday, November 27, 2003 4:22 AM
To: benzene-erp@listserve.api.org; jarnotb@api.org; jmricewas@aol.com; patrickbeatty@chevrontexaco.com;
Cagen, Stuart Z SCC-HSE
Subject: RE: Shanghai ERP - Baruch Brody has resigned due to ill health

Dear Bruce M. Jarnot,

I suggest that the ethical expertise within the study oversight group will be strengthened. Therefore, a replacement for Baruch Brody is necessary. This strengthening in ethics will be - in the end - also in the interest of this challenging study.

I propose following US/ CND ethicist candidates for your selection:

Prof. Greg Koski, formerly Director of OPRR of DHHS in Washington DC now back as a professor of anesthesia, Massachusetts General Hospital, Boston MA (gkoski@partners.org)

Dr David Lepay, Good Clinical Practice Program, OSHG, Office of the Commissioner, US Food and Drug Administration, Rockville, MD (dlepay@oc.fda.gov)

Dr. Ellen W. Clayton, Director, Genetics and Health Policy Center, Vanderbilt University, Nashville, Tennessee (

ellen.w.clayton@vanderbilt.edu)

Dr. Charles Weijer Department of Bioethics Education and Research,
Dalhousie University, Halifax, Nova Scotia, Canada (charles.weijer@dal.ca)

Dr David Wendler, Dept of Clinical Bioethics, National Institute of Health, Bethesda, Maryland (
dwendler@nih.gov)

I know all these candidates from the work on ethics and biomedical research within the CIOMS activities.

With best regards,

Juhana E. Idänpään-Heikkilä, MD, PhD
Secretary-General
Council for International Organizations of
Medical Sciences (CIOMS)
c/o World Health Organization (WHO)
CH-1211 Geneva 27, Switzerland

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

From: Juhana Idänpään-Heikkilä [mailto:juhana.idanpaan@pp.fimnet.fi]
Sent: Sunday, 23 November 2003 12:49
To: idanpaanj
Cc: owcena@who.int
Subject: Fw: Shanghai ERP - Baruch Brody has resigned due to ill health

----- Alkuperäinen viesti -----

Lähettiläs: Bruce Jarnot
Vastaanottaja: benzene-erp@listserv.api.org
Kopio: Patrick Beatty (E-mail) ; Stuart Cagen (E-mail)
Lähetetty: 20. marraskuuta 2003 21:31
Aihe: Shanghai ERP - Baruch Brody has resigned due to ill health

Benzene Health Research Consortium (BHRC) Ethics Review Panel -

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".

I would like to solicit the ERP's preferred course of action, in order to carry your collective opinion forward to the Consortium Oversight Committee...

1) Should a replacement US ethicist be recruited, maintaining original regional balance (Europe, China & US) and panel membership, and vote a new Chair? If so, can you identify a candidate ethicist for recruitment?

2) Or, should the ERP remain an independent, 2-member panel and vote a new Chair?

3) Or, given that the most active phase of ethics review was at the front-end of this study, and now that the work load on both ethics and scientific review panels has moderated, should the external panels integrate under the leadership of Jerry Rice? Both groups worked well together in this fashion at the August Asilomar meeting, and "topic lead" can be deferred to members having that specific expertise - with ethicists working ethics issues, as currently done within the science review panel for issues regarding biostatistics, molecular markers, industrial hygiene and other specialties.

Best Regards - Bruce.

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