From:	George Woodall <Woodallg@api.org>
Sent:	Thursday, January 24, 2002 7:04 PM (GMT)
To:	Richard Irons (E-mail) <richard.irons@uchsc.edu>; 'Wayne.Stillman@UCHSC.edu'
Cc:	Baruch Brody (E-mail) <bbrody@bcm.tmc.edu>; 'BenzConsort-TC@listserve.api.org' <BenzConsort-TC@api.org>
Subject:	FW: draft of IRB report
Attach:	APIIRBREPORT.wpd; EthicsReportOnProtocols22January2002.doc

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To all,
I remember that Dr. Irons had problems converting the WordPerfect document of this report in the last version, so I have converted to a Word document and attached. Additionally, the addresses shown on the message below looked as though they may have not gone through, and therefore I have included those addressees in this e-mail (Patrick is part of the listserve address list). I also included Dr. Stillman as Dr. Irons is now in China.

Regards,

George M. Woodall, Ph.D.
Senior Toxicologist
American Petroleum Institute
1220 L Street, NW
Washington, DC 20005

Tel. (202)682-8067
Fax. (202)682-8031
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Visit the New www.api.org.

-----Original Message-----
From: Dr. Baruch Brody [mailto:bbrody@bcm.tmc.edu]
Sent: Wednesday, January 23, 2002 11:33 PM
To: Woodallg@api.org
Cc: PatrickBeatty%chevrontexaco.com.Richard.IRONS%UCHSC.edu.bbrody@bcm.tmc.edu
Subject: draft of IRB report

Attached is my draft of the IRB report. I took the *December 11 summary report* (with a few useful edits suggested by George) and compared it to the protocols, which I finally got on *January 18 from Rich.*

The bolded points are a few small changes which Rich needs to make to get the protocols in full compliance with the summary report.

Once that is done, I can issue a final report saying that everything is done; I don't need the whole protocol again; just the pages on which the changes are made.

BARUCH

January 22, 2002

To: George Woodall,
American Petroleum Institute

Richard Irons
University of Colorado Health sciences Center

From: Baruch Brody
Baylor College of Medicine

Re: Ethics Review of Jan 18 Version of Two Protocols

The two protocols submitted by Dr. Irons are the major part of a larger set of studies, which also includes a case control study of AML/NHL. The three studies have been reviewed together through the whole API sponsored ethics review process, which I have headed. However, the comments provided in this report are applicable only to the protocols of Dr. Irons, since that case control study will be reviewed by a separate IRB.

The following major decisions were reached in our ethics review and have, as noted below, been incorporated into the protocol:

benefit to the community: To begin with, the laboratory being created will leave Shanghai with a state of the art clinical laboratory and local personnel trained to run it (p. 14 of protocol). Moreover, there will be modest financial provisions for continuing consultative support after the project is completed **(not in protocol, but in project budget as last discussed with our group)**. So there will be an immediate benefit to the community from the project. Moreover, commitments have been obtained from local officials that the resulting data will be used to strengthen local standards for benzene exposure (p. 115 of protocol).

benefit to subjects: In the disease progression study, attending physicians will be identified at clinic visits and will be notified of clinically relevant findings (p. 28 of protocol) Patients found to have developed benzene poisoning will be followed to insure that they are removed, as per Chinese law, from the benzene exposure workplace **(needs to be added on pp. 115-16)**. So there will be real clinical benefits to the subjects from their participation.

payments to subjects to avoid exploitation and coercive offers: Our primary concern was to insure that the subjects not be exploited by being underpaid for their participation, rather than on insuring that they not be coercively induced into participating by overpayment. In general, they will be paid amounts that are similar both to payments in the U.S. and in China. The payments for filling out the questionnaire will go directly to the subjects. To avoid legal issues in China, the payments for all other aspects of participation will go to the clinical coordinators and/or the pathologists who will be responsible for insuring that they are used to pay the subject's non research related medical expenses pp. 29-30 of protocol **with the need to add the point about the responsibility of the clinical coordinators/pathologists).**

protection of confidentiality: The clinical database from the diagnostic laboratory will of necessity contain identifiers of the subjects. Access to information in that database will be governed by the usual rules of confidentiality. The databases for the various studies will be separate from this clinical database and from each other. Data from the clinical database will be transferred to relevant research databases only after the subjects consent to participate in the relevant study. The research databases will not use the names of subjects, but will use codes whose linkage to the subjects will be in a separate file. Only a limited number of individuals will have access to all the databases. At the end of the studies, an additional database containing biological material, linked research data, and linked clinical data will be constructed to support future research, but it will contain no identifiers and no linkages to subjects (pp. 56-57 and 101 of the protocol).

informed consent: There will be separate consent forms for subjects and controls in each study. The purpose of the research and the role of the participants (as subjects or as controls) will be spelled out. These consent forms will clarify exactly what would be done as part of normal clinical practice and what will be done only if the subjects agree to participate in research. The financial arrangements will be clarified in the consent form as will the confidentiality arrangements (all this is done in the many consent forms in the protocol **except that the confidentiality arrangements for separating the clinical and the research databases, etc could be better explained).**

information about HIV: Information about HIV status obtained as part of standard clinical practice will be in the clinical database, will be transferred to the research database for those consenting to be in the research, and will be reported in accordance with Chinese law. This will be explained in the consent form **(done except that the reporting by the clinician to the Chinese authorities is not mentioned).**

control of publication of results: although the sponsors will have the opportunity to comment on the publication of results, the investigators have final control over all results to be presented or published (p 27 of protocol).

ongoing ethics review: the sponsors will create a four-person Ethics Review Panel (one US, one European, one Chinese, plus at least one representative of the workers/labor) to review both the final version of all the protocols and the ongoing research to see that these understandings have been implemented. There will be regular interaction between the Ethics Review Panel and the Scientific Review Panel **(alluded to at several places but where is it explicitly atated?).**

This report completes this review of protocols phase of the work. All future work should be part of the work of the ongoing Ethics Review Panel.

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